HUMAN RESEARCH

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Human Research

NOT FOR PUBLICATION

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George J. Alexander

HUMAN RESEARCH

Introduction

Throughout the ages scientific development has followed a definite pattern. From early days when the mere observation of nature produced fundamental scientific principles, men of science have achieved increasingly complex innovations, albeit at the price of human participation and increased risks to personal safety. At this moment in the twentieth century, man is exploring the lower depths of the earth through oceanographic studies, and is simultaneously seeking the outer reaches of the universe through space exploration. The dangers involved as man embarks upon these studies of the vast unknown are undoubtedly greater than ever before.

So great is the threat to man's safety as he seeks survival in these unnatural environments that he dares not leave his familiar surroundings until extensive experimentation and testing are completed. The correlation between progress and the risks involved in that pursuit thus demands that human beings, both the healthy and the unhealthy, act as subjects of scientific research. In the context of medical experimentation, one writer states this proposition in the following manner:

> In the coufse of biological and medical investigation, it is eventually both <u>necessary and proper</u> that human beings, individually or in groups, serve as the means by which a scientific assumption may be validated. Only by so extending

> the study of human physics and chemistry and disease can we render the benefits of medical research to society as a whole. (Ladimer, Ethical and Legal Aspects of Medical Research on Human Beings, 3 Jour. of Public Law 467, 468 (1954))

Numerous legal issues arise, however, in connection with research involving human beings. Problems involving consent, liability, and medical safeguards are most prominent. The purpose of this paper is to trace the development of legal thinking in this area at the NASA-Ames Research Center, Moffett Field, California, where various experiments involving human subjects are in progress, for the purpose of enabling man to reach his goal of conquering outer space.

I. A Broad Look at Ames' Policy

A glance at the history of the Ames policy regarding human research reflects not only an attempt to promulgate meaningful standards in this area at Ames, but also a diligent effort to effectuate agency-wide regulations. Such a suggestion was proposed in the Glazer memo of July 15, 1966, entitled "Use of motion simulation devices at Ames for controlled human research." (Appendix # 4) In section two, reference is made to an attached draft of a proposed Public Health Service regulation with the following commentary thereon:

> Parts of the draft may provide some basis for the formulation by NASA of agency-wide standards

governing controlled human research. In view of the fact that controlled human research has been undertaken by NASA at other field installations in addition to Ames I submit that the formulation of procedures and standards for the protection of subjects should be instituted on an agency-wide basis.

Efforts at implementing agency-wide standards can be observed in the November 2, 1966 memo (Appendix # 6) and in the November 28, 1966 memo entitled "Discussions at NASA Headquarters in connection with agency-wide instruction governing human research." (Appendix # 7) The latter document, which "contains minimum agency-wide requirements," (Id. at p. 1, paragraph 4. See also, p. 1 of April 20, 1967 memo from Glazer to Loren Bright, Appendix # 9, where the agency-wide proposal is discussed) constituted Ames policy until January 15, 1968, when it was superseded by Ames Management Manual 7170-1. (Appendix # 11)

While significant changes were introduced in the January, 1968 regulation, the agency-wide focus of Ames remained intact. Several proposals resembling AMM 7170-1 had been previously forwarded to NASA Headquarters in Washington in Ames' continuing effort to delineate more explicit standards and safeguards, and the Dembling memo of August 23, 1967 (Appendix # 10) is in large part a compilation of Ames' suggestions.

In sum, Ames has been a leader in the formulation of

agency-wide standards regarding human research. The other space centers in this country have continually looked to Ames for guidance in this area. AMM 7170-1 is an excellent document, and its ability to provide succinct standards readily acceptable by members of the medical profession is attested to by the Glazer letter of August 5, 1968 regarding the Stanford University Cardiovascular System study (Appendix # 12) and the August 8, 1968 response thereto in which significant changes, in conformity with AMM 7170-1, were made in the Grant Application (Appendix # 13).

II. A Look at the Development of Specific Legal Issues

A. Definition of "Human Research"

The term "experimentation" has over the years been judicially construed by the courts, but it has been continually equated with professional disregard or negligence, and has not been distinguished from "human research." Clearly a distinction between the terms must exist, for as the situations have arisen in litigation thus far, "experimentation" has involved the patient seeking out the physician for diagnosis or treatment, and in situations involving rather common modes of treatment. The normal "human research" situation, on the other hand, involves the researcher seeking out the subject and the implementation of relatively novel techniques, (See Ladimer, Ethical and Legal Aspects of Medical Research on Human Beings, 3 Jour. of Public Law 467 (1954))

In the absence of a judical definition of "human research," legal and medical scholars have advanced their notions concerning the components of the phrase. For example, Ladimer, in his article Ethical and Legal Aspects of Medical Research on Human Beings, cited above, proposes this definition:

> For our purpose, human research in medical science comprehends an investigation or observation by a professionally trained biological or medical scientist on or involving use of human beings, healthy or ill, primarily for the advancement of knowledge. (Id. at 472)

The Ames definition of "human research" has undergone several revisions. An early statement appears in section 1 of the Glazer memo entitled "Use of motion simulation devices at Ames for controlled human research," dated July 15, 1966 (Appendix # 4), and it largely resembles the above Ladimer definition:

> In contradistinction to the case law concept of 'experimentation,' 'human research' comprehends an investigation or observation by a professionally trained biological or medical scientist on, or involving the use of, human beings healthy or ill primarily for the advancement of knowledge rather than for the benefit of a patient. Human Research, therefore, connotes the use of a human being as a subject rather than a patient.

Subsequently, in section 5 of the Management Instruction dated October 19, 1966, which is attached to the November 2, 1966 document (Appendix # 6) the following definition was adopted:

As used in this Instruction:
a. 'Human research' means any test or experiment which may cause a human subject to suffer stress, pain, damage to health, physical injury, personality or emotional disorder, or death.

Oddly, the "Meeting of November 1 to consider proposed NASA Headquarters Management Instruction entitled 'Human Research Policy and Procedures' (Appendix # 6) elected to eliminate the definition sections in the Instruction. However, by the time the Instruction "Use of Persons in Aerospace Research" (See Memo, November 28, 1966, Appendix # 7) replaced the "Human Research Policy and Procedures" proposal, the definition of "human research" was reinstated, albeit in slightly different form. Section 2 stated:

For the purpose of this Instruction 'human research' means 'any research, development, test, experiment, or evaluation procedure on man which may expose him to distress, pain, impairment to health, physical injury, or death.

Of note is the addition of various descriptive modes of research, but the omission of personality or emotional disorder as a possible resultant adverse effect of the study.

The current Ames definition of "human research" incorporates all of the elements of former statements, and is embodied in Section 4 of Ames Management Manual 7170-1. It reads as follows:

> Notwithstanding other technical usage, the term 'Human Research,' for purposes of this article, means any test, experiment, or other evaluation procedure in the course of which, or as a result of which, a human subject may be exposed to conditions which could reasonably be expected to cause distress, pain, impairment of health, physical injury, personality or emotional disorder, or death.

B. Voluntary Informed Consent

The area presenting the most difficult and complicated problems for those engaged in human research is voluntary informed consent. As distinguished from the normal therapeutic situation, where care of the patient is the primary concern of the physician and where consequently a high degree of trust is built into their relationship, in the realm of nontherapeutic treatment, the primary aim of the physician is increased knowledge, and as a result, a much more formalized doctor-patient relationship must necessarily exist. In the therapeutic situation, the doctor is guided by his professional judgment in regard to how much, if anything, he should divulge in view of his patient's condition. In other words a degree of implied consent can be readily inferred. On the other hand, in cases of nontherapeutic treatment, there must be full disclosure of the doctor's aims, of the proposed treatment, and of the risks involved, and an express consent on the part of the subject. (See Freund, Ethical Problems in Human Experimentation, 273 New England Journal of Medecine 687 (September 23, 1965)

As one writer states:

> The essence of the claim to privacy is the choice of the individual as to what he shall disclose or withhold, and when he shall do so. Accordingly, the essential privacy-respecting ethic for behavioral research must revolve around the concept of consent. (Ruebhausen and Brim, Privacy and Behavioral Research, 65 Colum. L. Rev. 1184, 1198 (1965))

Crucial issues arise when trying to determine whether a consent was voluntary and informed. Initially one must question whether the subject possessed the requisite capacity to consent. Problems involving children and the mentally impaired immediately come to mind in this regard. Next, assuming capacity on the part of the subject, one must determine whether there was full disclosure by the physician, recognizing the difficulty of the layman in comprehending medical intricacies. In addition, one must consider whether any element of duress was present, such as offering large payments to the subject, or promising parole to the criminal subject. These and other inquiries are essential in affording the subject the protection he truly deserves, as they assure that the consent granted was totally voluntary and informed. (See Mulford, Experimentation of Human Beings, 20 Stanford L. Rev. 99 (1967))

In regard to Ames policy in this area, there has never been any doubt that a voluntary, informed consent is

essential to the successful implementation of human research. For example, the Johnson memo of April 5, 1961 stipulates:

> Our research does emphasize, however, the importance of obtaining from the subject a freely given consent after thoroughly explaining to him the nature of the experiment and the risks to which he will be exposed. (Appendix # 1)

The crucial problem, however, has been the development of standards capable of meeting that requirement.

The Glazer memo of July 15, 1966 (Appendix # 4) states the need for consent by the subject, and refers to the attached statement by Edward J. Rourke urging consent in writing. According to Rourke:

> The one aspect which we have retained from the original draft . . . is the requirement that consent of the subject be in writing. We strongly urge its retention, not to replace the need for good oral understanding between subject and investigator, but because proof of consent is vital to the legal basis for the entire participation and proof of consent will be either difficult or impossible if there is no written consent signed by the subject.

The first Management Instruction provisions regarding voluntary informed consent were formulated in the October 19, 1966 Instruction, which is attached to the November 2, 1966 document, (Appendix # 6) It reads as follows:

> a. The freely given informed consent of the subject is essential.
>
> b. Before a subject is permitted to give his consent, the contemplated human research must be explained to the subject, in language understandable to him. This explanation should include the

> nature, duration, and purpose of the human research, the manner in which it will be conducted, and all foreseeable inconveniences, discomforts, and/or risks to the subject which might result from the human research. If the nature of such inconveniences, discomforts or risks is not known beforehand, this fact should be made known to the subject.
>
> c. The subject must be informed of any parts of the human research which cannot be stopped or controlled by either the subject or the person conducting the human research prior to the scheduled conclusion.
>
> d. Subjects must give their consent in writing in such form as will indicate on its face that the subject has been fully informed of, and voluntarily accepts, the risks involved. See Attachment A for a suggested form of consent.

Dissatisfaction with this section led to a complete revision upon implementation of the Management Instruction of November 28, 1966. (Appendix # 7) No standards were promulgated in the Instruction itself. Instead a note to the Headquarters reviser appeared, with the following brief remarks:

> No substantive comments except that an adaptation of the language in the Nuremberg Code might be preferable. This is an editorial matter.

The Nuremberg Code had been highly publicized and was a recognized standard in the area of human research. Thus, Ames adopted its provisions regarding voluntary consent, which read as follows:

> The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power

of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be known to him the nature, duration, and purpose of the experiment, the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment.

In 1968, with the adoption of AMM 7170-1, the voluntary informed consent provision was changed once again. (Appendix # 11) The section now reads as follows:

a. Except as provided in subparagraph 8b:

(1) No human research may be conducted unless the subject voluntarily agrees to participate in the human research, has freely given his informed consent in accordance with this subparagraph 8a and has the legal capacity to so consent.

(2) No consent given by a subject shall be deemed informed unless, prior to the giving of consent, the proposed human research is explained to the subject in language understandable to him. Such explanation must include the nature, duration, and purpose of the human research; the manner in which it will be conducted; and all foreseeable risks, inconveniences, and discomforts to the subject that might result from the conduct of the human research. If the nature of such risks, inconveniences, or discomforts is not known, this fact must be made known to the subject. In addition, the subject must be informed that he may withdraw from the human research at any time, or if this is not in fact the case (because the circumstances of the experiment make such withdrawal unwise, dangerous, or impossible), he must be so advised.

(3) A subject must give his consent in writing in such form as will indicate that he has been fully informed of, and voluntarily accepts, the risks, inconveniences, and discomforts which may be involved.

(4) A person who is a minor or who is without legal capacity to give his voluntary informed consent shall not be a subject of human research without specific authorization in writing signed by the NASA Administrator.

b. The Director may waive some or all of the requirements of subparagraph 8a if he determines that, due to the requirements of the proposed human research (e.g., necessity that the subject be unaware that he is participating in an experiment; nature of experiment requires use of minors when otherwise authorized), such research would be seriously hampered by any of the requirements of subparagraph 8a.

This provision goes beyond Nuremberg in three important respects: (1) There is an explicit requirement of written consent; (2) The Director is given authority to waive some of the general requirements in certain instances; and (3) Specific reference to minors is made. The importance of the latter provision is that while it is highly unlikely that minors will be utilized as subjects of human research at Ames, the door remains open for the remote possibility of child research becoming a reality.

The present section is well drafted, incorporating all of the safeguards deemed important by writers in the field. The effectiveness of the provision becomes most evident when viewed in the context of actual application. The Special Consent Form attached to the letter of August 8, 1968

regarding the Cardiovascular System study (Appendix # 13) serves that purpose. The detailed description of the proposed research ensures a more fully informed consent than was the case with the generally vague and broad forms employed earlier. (See e.g., forms attached to the Glazer July 15, 1966 memo, Appendix # 4; forms embodied in the September 30, 1966 document, Appendix # 5)

The forms attached to the November 28, 1966 memo (Appendix # 7) and the NASA-Massey Temporary Service, Inc. contract also seem to satisfy the requirements of AMM 7170-1. In sum, the Ames Research Center has made great progress in adopting meaningful standards in the very important area of voluntary informed consent.

C. Waiver of liability

Related to the problem of voluntary informed consent is the issue of waiver of liability. While a fundamental tort rule states that the consent of an individual injured or damaged will usually avoid liability, this principle is not invoked in the human research situation. Ames has consistently taken a position against requiring waivers of liability from research subjects. This section shall relate instances of Ames commentary on this subject.

As early as 1961, Ames took a critical viewpoint towards release of liability. (Appendix # 1) In a letter dated April 5, 1961, the General Counsel disapproved of a pro-

posed release, saying:

> Since we are advised that the centrifuge tests are conducted in furtherance of the Government's approved space program, as a matter of policy, it would seem inappropriate to seek release of the Government at the expense of those participants who are contributing to the Government's program.

A 1964 Dembling memo (Appendix # 2) stated in regard to waivers of liability:

> It is our opinion as a matter of Government policy, that waivers of liability should not be required from the participants in hazardous tests. If an accident should occur, the burden of risk should not be borne solely by the injured individual. Also, such waivers have the detrimental effect of discouraging participation in the tests.

Subsequently, the July 15, 1966 Glazer memo entitled "Use of motion simulation devices at Ames for controlled human research" (Appendix # 4) refers to the 1961 letter quoted above and states in section four:

> To comport with established NASA policy 'consent forms' must not contain statements requiring the subject to waive, or otherwise release, rights against the Government, third parties, or individuals in the event of misadventure.

Similar policy statements may be located in section 7c of the proposed Management Instruction of October 19, 1966 (Appendix # 6), section 5B of the Management Instruction attached to the November 28, 1966 memo (Appendix # 7), and section 5 of the Dembling memo dated August 23, 1967 (Appendix # 10), which has been embodied in section 5 of

Ames Management Manual 7170-1 (Appendix # 11) and reads as follows:

> Apart from the obtaining of a proposed subject's consent in accordance with paragraph 8, no subject shall be asked to waive any rights that may arise in connection with any injury, loss, or death suffered by the subject as a result of human research.

Thus, it can be readily observed that Ames has uniformly been critical of waivers of liability, and that this issue raises no particular problem any longer.

D. Additional Safeguards

1. Group review of the project

An essential ingredient of any human research project is prior review and approval of the proposal by a group of medical experts and/or intelligent laymen. In view of the high degree of risk to the subject and the nontherapeutic purpose of the experiment, a necessity arises for confirmance of the principal investigator's opinions by an enlightened objective body. As one writer states while discussing non-therapeutic treatment:

> Here, though it may be hard for us to admit it, the issues transcend the expertise of any single individual representing any single professional discipline. Legal considerations are involved, as well as moral and ethical considerations broader than any professional code. Specifically, when the research proposal implies conflict with the public ethic,

> the responsibility for the decision is too great for the scientist alone. (Stewart, An Invitation to Open Dialogue, Saturday Review, pp. 43, 44 (July 2, 1966))

The Public Health Service has released a policy statement requiring group assessment of each project prior to investigation. Such review shall consider (1) the rights and welfare of the subject, (2) the appropriateness of the informed consent, and (3) the risks involved and the potential medical benefits to be derived. (See Public Health Service Policy for the Protection of the Individual as a Subject of Investigation, U.S. Department of Health, Education and Welfare (March, 1968))

A statement describing the composition of the review board at Ames appears in the Harold Sandler memo of June 6, 1966 (Appendix # 3). He states in paragraph four therein:

> The Board should serve the dual purpose of defining the medical-legal responsibilities of this Center for human volunteers as subjects for research and of defining the medical safety criteria and procedures to be used by all investigators and medical monitors when using human test subjects. Aside from legal representation, this committee must contain individuals with specialized and personal experience in clinical research. A Ph.D. degree does not satisfy medical-legal requirements. Only M.D.'s with at least two years of clinical experience and, preferably those individuals with personal experience with motion simulators, should be chosen. The Board should include at least three M.D.'s of this caliber and be sufficiently flexible to include or replace appointed individuals by personnel with more depth of experience when the occasion arises.

The medical personnel on the board is described with some specificity in the above memo, while the legal representation

is lightly glossed over. The Glazer memo of April 20, 1967 to Mr. Loren G. Bright (Appendix # 9) discusses this problem in paragraph three:

> Paragraph 3 of the Rathert proposal discloses that a 'medical' review board will, among other things, approval (sic) or reject proposals to proceed with a given line of research. Why a 'medical' review board? This departs from the 'jury of peers' idea espoused in some of the literature concerning approval, 'to go ahead', with a line of human research. The 'Board' should be composed of laymen as well as scientists; this is not to say, however, that laymen should be in the majority. I believe that it would be a healthy system of 'checks and balances' if one, or a couple of, laymen served on the board. And if a given line of 'human experimentation' is simply at war with their 'good common sense', the laymen involved should vote against it notwithstanding 'scientifically conclusive' arguments that the experiment ought to proceed. The Board should not be a 'blue ribbon panel' of scientists.

Section four of the Management Instruction attached to the November 28, 1966 Glazer memo (Appendix # 7) designates several review functions to a specified NASA official. The January 15, 1968 AMM 7170-1 (Appendix # 11) goes further by requiring a detailed protocol (See Attachment A to 7170-1) to be submitted to the Director prior to commencement of the investigation. The Director is instructed to consider whether:

(1) The importance of the objective of the research outweighs the inherent risks to the subject.
(2) The subject of the human research will be unnecessarily exposed to risk of injury, discomfort, or inconvenience.
(3) The subject or his representatives will receive adequate compensation, by reason of

> insurance, workman's compensation, or the like, in the event the subject suffers any loss, injury, or death as a result of the human research.

In addition, section 10 authorizes the Director, at his discretion, to appoint an advisory board to aid him in his decision.

The most recent statement concerning a review board appears in Attachment A to the August 8, 1968 memo from Sutton to Glazer (Appendix # 13) in regard to the Stanford University Cardiovascular System study. Therein one finds a document entitled "Institutional Assurance on Investigations Involving Human Subjects, Including Clinical Research," which adopts the policies announced by the Public Health Service, and is in compliance with the terms of AMM 7170-1.

2. Presence of two physicians

Writers have suggested, as an additional safeguard, the presence of a monitor during the investigation whose sole concern is with the welfare of the subject. (See Mulford, Experimentation of Human Beings, 20 Stanford L. Rev. 99 (1967)) Such a procedure has the advantage of avoiding a conflict of interests problem on the part of the principal investigator. AMM 7170-1, section 7 (Appendix # 11) provides for extensive examination of the subject by a physician, and in Attachment A thereto requires the protocol to describe the availability of a physician during the course of the investigation.

3. Screening of reports prior to publication

It has been proposed by some writers that all reports by investigators should be screened prior to publication, for the purpose of detecting violations of the subject's rights. As publication is the ultimate goal of all researchers, it is alleged that such a safeguard will ensure self-restraint. (See Mulford, Experimentation of Human Beings, 20 Stanford L. Rev. 99 (1967); Beecher, Documenting the Abuses, Saturday Review, p. 45 (July 2, 1966)) As of this moment, Ames has not promulgated such a rule.

Conclusion

As indicated earlier, the area of human research has yet to come under judicial scrutiny. While the term "experimentation" has received court interpretation, it has been construed within the limited confines of medical malpractice. Consequently, it can be predicted that the standards promulgated by Ames and by other institutions will ultimately have to face the test of legal sufficiency. Favorable results seem likely.

APPENDIX #1

AG/laf

April 5, 1961

Ames Research Center
Moffett Field
California

Attention: Mr. Arthur B. Freeman
Administrative Management Officer

Re: Hazardous Experiments Involving Humans

Dear Mr. Freeman:

After reviewing the release proposed for execution by contractor personnel participating in NASA flight simulator tests, we would recommend against its use by Ames for several reasons.

As drafted, that release would relieve both the Government and the agents, employees, etc., of the Government from liability. Since we are advised that the centrifuge tests are conducted in furtherance of the Government's approved space program, as a matter of policy, it would seem inappropriate to seek release of the Government at the expense of those participants who are contributing beneficially to the Government's program.

We can appreciate the concern of doctors and other Government personnel as to possible personal liability resulting from the conduct of these tests and, accordingly, have looked into this question. Our search has revealed no case holding a physician liable for injury to a competent adult volunteer subject arising from experiments conducted in accordance with carefully considered safety standards. Those cases where liability has been established have factually involved a patient's change of negligence against his physician, and despite some language to the contrary,

seem little different than the normal malpractice action. In such cases, the proposed release would probably be ineffective as a bar to liability.

Our research does emphasize, however, the importance of obtaining from the subject a freely given consent after thoroughly explaining to him the nature of the experiment and the risks to which he will be exposed. A written consent would be most valuable, tailored as closely as possible to the particular experiment and risks involved, and we offer our assistance in its preparation.

Meanwhile, we shall study further to assure ourselves that everything possible is being done to lend NASA support to those charged with the responsibility of carrying out the agency's experiments. You may wish to examine further specific problems, and I shall be happy to hear from you or to discuss them first hand whenever you are in Washington.

Very truly yours,

John A. Johnson
General Counsel

LAF/rks

STANDARD FORM NO. 64

Office Memorandum • UNITED STATES GOVERNMENT

TO : Mr. Paul Dembling
NASA Headquarters

DATE: Feb. 21, 1961

FROM : William V. Shaw - Ames

SUBJECT: Hazardous experiments involving humans

Dear Paul:

Referring to the recent telephone conversation Art Freeman had with you regarding the legal and medical questions our people are raising in connection with experiments involving human subjects, I am enclosing a draft of a release designed primarily to protect our personnel and the Government when contractors and other outside personnel participate in our flight simulator tests. If you believe as we do that such a release may have some force and effect in the event of mishap, we would appreciate your reviewing it for legal sufficiency and giving us your comments on your forthcoming visit to Ames.

I understand from Art that the period of your visit was not set when he talked to you. As it turns out, two of the people most interested in this matter and to whom we think you would like to talk--Dr. Harald A. Smedal and George Rathert--will be on extended travel on and after March 14, 1961. Dr. Smedal will be in Johnsville, Pennsylvania, working on some of the very tests in question until May 2, 1961. Thus, from our standpoint, the best time for your visit would be early in March.

We are looking forward to seeing you again.

WVS

Enclosure

AMES RESEARCH CENTER

NASA

RELEASE

Whereas, I, _____, an official representative of _____, acting under the instructions of that organization will be riding moving-base flight simulators at the Ames Research Center, and whereas I have been warned that maximum accelerations anticipated on this project are:

A_X = _____ A_θ = _____

A_Y = _____ A_ϕ = _____

A_Z = _____ A_ψ = _____

and that limiting devices have been set to avoid exceeding these accelerations, and whereas I have been further warned that equipment malfunction and/or safety device failure could result in exceeding these accelerations, particularly in the form of impact stops, which are in excess of normal safe practice, and whereas I do so entirely on my own initiative, risk, and responsibility, relying on medical advice given me by physicians employed by _____; now, therefore, in consideration of the permission extended to me by the United States through its officers and agents to take such action, I do hereby, for myself, my heirs, executors, and administrators remise, release and forever discharge the Government of the United States and all of its officers, agents, and employees, acting officially or otherwise, from all claims, demands, actions, or causes of action on account of my death or on account of any injury to me which may occur from any cause during my presence in the moving base simulator during this project, or continuances thereof, or any after

effects resulting therefrom.

Signature

Witness

Name of person to be notified in emergency

Witness

Address of person to be notified in emergency

COPY

COPY

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APPENDIX #2

CIRCULATED TO FIELD COUNSEL

Noted:
Mr. Sohier

TO : Manned Spacecraft Center
Attention: Mr. J. Wallace Ould
Chief Counsel

FROM : Office of General Counsel

SUBJECT : Legal aspects of hazardous experiments and tests involving humans

THE PROBLEM

In your memorandum, dated February 11, 1964, you invited our comment on and discussion of several questions pertaining to the legal aspects of hazardous experiments and tests involving unusual physical conditions for humans, such as confinement in a centrifuge or test chamber and subject to vacuums or extreme temperatures. Specifically, you asked the following three questions:

(1) Are medical personnel, detailed to NASA by DOD, inhibited by DOD regulation, or State law, from affording monitoring, first aid, etc. to Government or Contractor personnel?

(2) Policy-wise, should waivers of liability be requested from Government or contractor personnel subjected to unusual conditions?

(3) Is it advisable to undertake contractual provisions under which the employer-contractor would agree to hold harmless the Government? Or to require that the carrier of his Workmen's Compensation Insurance waive any rights of subrogation against the Government?

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1. Federal or State Restrictions on Medical Activities

(a) General Authority to Conduct Research Experiments

Under the Space Act, the National Aeronautics and Space Administration has been given broad authority to conduct the space program of the United States and to perform whatever activities are necessary in connection therewith (42 U.S.C. §§2451, 2473). The Supremacy Clause of the Constitution of the United States (Article VI, Clause 2) provides that the Constitution and Laws of the United States shall be the supreme Law of the Land, and, therefore, space activities can be carried on without regard to the laws of any State. McCullough v. Maryland, 4 Wheat 316 (1819); Paul v. United States, 371 U. S. 245 (1963); Leslie Miller, Inc. v. Arkansas, 352 U.S. 187 (1956); Public Utilities Commission v. United States, 355 U. S. 534 (1957); Johnson v. Maryland, 254 U. S. 51 (1920). See also Report of the Interdepartmental Committee for the Study of Jurisdiction over Federal Areas Within the States (submitted to the Attorney General: Part 1, April 1956; Part II, June 1957).

Specifically, section 203(a) of our Act directs NASA to "(1) plan, direct, and conduct aeronautical and space activities"; and "(2) arrange for participation by the scientific community in planning scientific measurements and observations to be made through use of aeronautical and space vehicles, and conduct or arrange for the conduct of such measurements and observations . . . ." Thus, there can be no doubt of NASA's authority to conduct experiments relating to man's capacity for space flight and to utilize the services of scientific and medical specialists in connection therewith. We can see no basis upon which State law could interfere with or restrict such experiments.

(b) Military Regulations

We have talked with several lawyers and doctors in the Department of Defense and they were unaware of

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any regulations which would prohibit military medical personnel assigned to NASA from participating in scientific tests or research activities. The only possible restriction they mentioned would be against giving general medical treatment to contractor employees (aside from first aid and emergency care), but we assume that this is not what you had in mind.

Nevertheless, no matter what military regulations may provide, they do not apply to military personnel assigned to NASA. Section 203(b)(12) of the Space Act authorizes NASA:

> (12) with the approval of the President, to enter into cooperative agreements under which members of the Army, Navy, Air Force, and Marine Corps may be detailed by the appropriate Secretary for services in the performance of functions under this Act to the same extent as that to which they might be lawfully assigned in the Department of Defense;

Pursuant to section 203(b)(12), an agreement was entered into between the Departments of Defense, Army, Navy, and Air Force, and the National Aeronautics and Space Administration, concerning the detailing of military personnel for service with NASA, which was approved by the President on April 13, 1959. The agreement (NASA Management Manual Instruction No. 2-3-3) provides, among other things, that military personnel detailed to NASA will be governed by NASA regulations, except for military discipline, leave, and flying requirements. The agreement states (Par. IV,(b)):

> Except as noted in (a) above, persons detailed or appointed to NASA will not be subject to direction or control by the Department from which detailed with respect to their duties and responsibilities with NASA. Personnel detailed to NASA will be governed by all appropriate regulations and directives of NASA.

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NASA, therefore, need not be concerned with military restrictions on medical personnel. During their period of assignment to NASA, detailed persons are not subject to direction or control from the military services with respect to their duties for NASA.

(c) Authority for Occupational Medical Care

In addition to its authority under the Space Act, NASA, under 5 U.S.C. 150 and 5 U.S.C. 759, is authorized: to establish health facilities for employees; to provide treatment of injuries and illnesses due to occupational causes; and to provide treatment for on-the-job emergencies. It is also the view of this Office, as set forth in the Memorandum for the Deputy General Counsel of February 25, 1964, signed by Sophie Cook and circulated to field counsel, that NASA, under section 203(b)(5) of the Space Act, may extend the use of its occupational medical facilities to contractor employees. There is no question, therefore, that hazardous test participants, regardless of whether they are NASA employees, servicemen, or contractor employees, may be given first aid and emergency medical care. Contractor employees can thereafter be transferred to a private hospital for further medical treatment, if necessary. Government employees may be transferred to a Government hospital pursuant to 5 U.S.C. 759 (Supp. IV), which provides as follows:

> For any injury sustained by an employee while in the performance of duty, whether or not disability has arisen, and notwithstanding that the employee has accepted or is entitled to receive benefits under the Civil Service Retirement Act, the United States shall furnish to the employee all services, appliances, and supplies prescribed or recommended by duly qualified physicians which, in the opinion of the Secretary, are likely to cure or to give relief or to reduce the degree or the period of disability or to aid in lessening the amount of the monthly compensation. Such services, appliances, and supplies shall be furnished by

> or upon the order of United States medical officers and hospitals, but where this is not practicable they shall be furnished by or upon the order of private physicians and hospitals designated or approved by the Secretary. For the securing of such services, appliances, and supplies, the employee may be furnished transportation, and may be paid all expenses incident to the securing of such services, appliances, and supplies, which, in the opinion of the Secretary are necessary and reasonable . . . .

In answer to your first question, therefore, we find no inhibition in State law or military regulation against providing monitoring and first aid services to Government or contractor personnel. Moreover, we understand that the research doctors and specialists who conduct such tests are not necessarily experienced in the treatment of accident victims. For that reason, we recommend that practicising physicians who are fully experiences in treating accidental injuries also be present when hazardous tests are being performed.

2. Waivers of Liability

It is our opinion, as a matter of Government policy, that waivers of liability should not be required from the participants in hazardous tests. If an accident should occur, the burden of risk should not be borne solely by the injured individual. Also, such waivers might have the detrimental effect of discouraging participation in the tests. H.R. 1159, a bill to provide extra pay for federal employees performing hazardous duty has passed the House and is pending in the Senate. Its purpose is to encourage employees to take part in activities such as space experiments. Requiring participants to sign waivers of liability would have the opposite effect.

Aside from policy considerations, the field of compensation for occupational injuries is covered by statute: namely, the Federal Employees Compensation Act (5 U.S.C. 751 et seq.) and the Workmen's Compensation Acts enacted in all fifty states.

The F.E.C.A. provides for compensation for any civil federal employee injured or killed in the performance of his duty &5 U.S.C. 751). Section 757 (b) of Title 5 provides that the liability of the United States under F.E.C.A. is exclusive and in place of all other liability of the United States to the employee or anyone entitled to recover on his behalf. See Johanson v. United States, 343 U.S. 427 (1952); and Patterson v. United States, 359 U.S. 495 (1959).

The coverage of the F.E.C.A. is very broad. Section 790 of Title 5, United States Code, defines the term "employee" to include "(1) all civil officers and employees of all branches of the Government of the United States . . . (2) persons rendering personal services of a kind similar to those of civilian officers or employees of the United States to any department, independent establishment, or agency thereof, . . . without compensation or for nominal compensation, in any case in which acceptance or use of such services is authorized by an Act of Congress, or in which provision is made by law for payment of the travel or other expense of such person . . . ." Other statutes provide compensation and other benefits to military personnel injured in the line of duty (e.g., 38 U.S.C. 301, 401, 501, 601, and 701 et seq.).

The Federal Employees Compensation Act and the military compensation acts, accordingly, would extend to every participant (except contractor employees), employed by the Government on a temporary or permanent basis, whether with or without compensation. The Bureau of Employees' Compensation, Department of Labor, is responsible for administering the act (5 U.S.C. 778, 783). The Bureau's regulations explicitly state that no waiver of the right to claim compensation is authorized (20 C.F.R. 1.24). The rules of the Bureau for processing claims are set forth in 20 C.F.R., Ch. 1.

The employees of NASA contractors are similarly protected by state workmen's compensation acts which provide statutory compensation for on-the-job injuries. When an injury to an employee is covered by these laws, "it is uniformly held that the statutory compensation is the sole remedy, and that any recovery at common law is barred." Prosser on Torts 384

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(2d ed.). Congress has extended such state laws to include federal territory within the states (40 U.S.C. 290). In Capetola v. Barclay White Co., 139 F.2d 555, cert. denied 321 U.S. 799 (1944), that statute was held to make the State act operable as to injuries to contractor employees on federal property, even without formal adoption of the federal act by the State legislature. See Wallach v. Lieberman, 219 F. Supp. 247 (D.N.Y. 1963).

In most instances, the workman's compensation acts, by their own terms, prohibit any attempts to obtain waivers or releases of the statutory benefits (58 Am. Jur., Workmen's Compensation, §49). Such prohibitions are valid. Alaska Packers Association v. Industrial Accident Commission, 294 U.S. 532. And even in the absence of express prohibition, attempted waivers would be invalid as being against public policy. 58 Am. Jur., supra; Carpenter v. Globe Indem. Co., 65 R.I. 194, 14 A.2d 235.

If there are participants or observers in the forthcoming hazardous tests who might possibly not be covered by F.E.C.A. or workmen's compensation, we should not attempt by waiver to deprive them of the relief that Congress has provided in the Federal Tort Claims Act (28 U.S.C. 1346, 2671-2680). Of course, the Government's liability under F.T.C.A. is limited to damages caused by the negligence of its employees while acting within the scope of their employment (28 U.S.C. 1346(b)). Also, the Government has been held not subject to absolute liability for damages arising from extra-hazardous activities. Dalehite v. United States, 346 U.S. 15; Strangi v. United States, 211 F.2d 305.

NASA, however, has the authority under section 203(b)(13) of the Space Act to settle claims not exceeding $5,000 against the United States for bodily injury or death resulting from the conduct of the Administration's functions, and the authority to report meritorious claims over $5,000 to Congress for its consideration. We have interpreted this provision to permit equitable consideration of such claims without incorporating traditional negligence concepts

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such as contributory negligence or assumption of risk. It is conceivable, therefore, that a situation might arise where NASA would be able to use section 203(b)(13) to settle a claim arising from a hazardous experiment, especially if other avenues of recovery were foreclosed.

3. Hold-Harmless Agreements

Contractual provisions under which a contractor would agree to hold the Government harmless seem inappropriate in the area of hazardous operations. As mentioned above, the Government's liability under the Federal Tort Claims Act is limited to negligence, and we question whether any attempt should be made to modify such liability. The possibility of recovery by a contractor's employee from the Government is further lessened by the general rule that the prinicpal employer is not responsible for the negligence of its contractors or subcontractors. See Wallach v. United States, 291 F.2d 69 (2d Cir. 1961), in which an employee of a painting contractor sued the Government to recover for injuries sustained when a scaffolding constructed by the contractor in a post office collapsed. The Court denied recovery, holding that the Government was not liable for the negligence of the independent contractor (id. at 69-70).

Recently, that principle was reaffirmed by the U. S. Court of Appeals for the Second Circuit. It held that the United States cannot be held liable under F.T.C.A. for injuries suffered by AEC contractor's employees from an explosion at the contractor's plant since the AEC's authority to supervise contractor's safety procedures is discretionary rather than mandatory. Blaber v. United States, (2d Cir. 5/28/64), 32 U. S. L. Week 2648-49.

Situations may arise, of course (negl), where the Government will be liable to contractor employees, but, if so, the Government should not attempt to contract out of its liability, The same principle applies to requiring insurance carriers to waive their right of subrogation against the Government.

Instead of attempting to limit Governmental liability, the question now being studied is whether the Government should indemnify contractors against the risks of catastrophic accidents resulting from its programs or otherwise assume the risks of such accidents. The trend seems to be toward the Government's assuming a larger share of the risk arising from its programs, rather than toward a lessening of Governmental liability.

It may be that these rather general observations do not answer the specific question you had in mind. If not, or if you desire more advice on a particular aspect of the problem, please let us know, and we will be happy to give further assistance.

"orig sgd by"

Paul G. Dembling
Deputy General Counsel

AG/RLH

AG/RLHiggins:dch
F-139

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Appendix # 2 p. 35

CIRCULATED TO FIELD COUNSEL

Noted:
Mr. Sohier

TO : Manned Spacecraft Center
Attention: Mr. J. Wallace Ould
Chief Counsel

FROM : Office of General Counsel

SUBJECT : Legal aspects of hazardous experiments and tests involving humans

THE PROBLEM

In your memorandum, dated February 11, 1964, you invited our comment on and discussion of several questions pertaining to the legal aspects of hazardous experiments and tests involving unusual physical conditions for humans, such as confinement in a centrifuge or test chamber and subject to vacuums or extreme temperatures. Specifically, you asked the following three questions:

(1) Are medical personnel, detailed to NASA by DOD, inhibited by DOD regulation, or State law, from affording monitoring, first aid, etc. to Government or Contractor personnel?

(2) Policy-wise, should waivers of liability be requested from Government or contractor personnel subjected to unusual conditions?

(3) Is it advisable to undertake contractual provisions under which the employer-contractor would agree to hold harmless the Government? Or to require that the carrier of his Workmen's Compensation Insurance waive any rights of subrogation against the Government?

any regulations which would prohibit military medical personnel assigned to NASA from participating in scientific tests or research activities. The only possible restriction they mentioned would be against giving general medical treatment to contractor employees (aside from first aid and emergency care), but we assume that this is not what you had in mind.

Nevertheless, no matter what military regulations may provide, they do not apply to military personnel assigned to NASA. Section 203(b)(12) of the Space Act authorizes NASA:

> (12) with the approval of the President, to enter into cooperative agreements under which members of the Army, Navy, Air Force, and Marine Corps may be detailed by the appropriate Secretary for services in the performance of functions under this Act to the same extent as that to which they might be lawfully assigned in the Department of Defense;

Pursuant to section 203(b)(12), an agreement was entered into between the Departments of Defense, Army, Navy, and Air Force, and the National Aeronautics and Space Administration, concerning the detailing of military personnel for service with NASA, which was approved by the President on April 13, 1959. The agreement (NASA Management Manual Instruction No. 2-3-3) provides, among other things, that military personnel detailed to NASA will be governed by NASA regulations, except for military discipline, leave, and flying requirements. The agreement states (Par. IV,(b)):

> Except as noted in (a) above, persons detailed or appointed to NASA will not be subject to direction or control by the Department from which detailed with respect to their duties and responsibilities with NASA. Personnel detailed to NASA will be governed by all appropriate regulations and directives of NASA.

NASA, therefore, need not be concerned with military restrictions on medical personnel. During their period of assignment to NASA, detailed persons are not subject to direction or control from the military services with respect to their duties for NASA.

(c) Authority for Occupational Medical Care

In addition to its authority under the Space Act, NASA, under 5 U.S.C. 150 and 5 U.S.C. 759, is authorized: to establish health facilities for employees; to provide treatment of injuries and illnesses due to occupational causes; and to provide treatment for on-the-job emergencies. It is also the view of this Office, as set forth in the Memorandum for the Deputy General Counsel of February 25, 1964, signed by Sophie Cook and circulated to field counsel, that NASA, under section 203(b)(5) of the Space Act, may extend the use of its occupational medical facilities to contractor employees. There is no question, therefore, that hazardous test participants, regardless of whether they are NASA employees, servicemen, or contractor employees, may be given first aid and emergency medical care. Contractor employees can thereafter be transferred to a private hospital for further medical treatment, if necessary. Government employees may be transferred to a Government hospital pursuant to 5 U.S.C. 759 (Supp. IV), which provides as follows:

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> or upon the order of United States medical officers and hospitals, but where this is not practicable they shall be furnished by or upon the order of private physicians and hospitals designated or approved by the Secretary. For the securing of such services, appliances, and supplies, the employee may be furnished transportation, and may be paid all expenses incident to the securing of such services, appliances, and supplies, which, in the opinion of the Secretary are necessary and reasonable . . . .

In answer to your first question, therefore, we find no inhibition in State law or military regulation against providing monitoring and first aid services to Government or contractor personnel. Moreover, we understand that the research doctors and specialists who conduct such tests are not necessarily experienced in the treatment of accident victims. For that reason, we recommend that practicising physicians who are fully experiences in treating accidental injuries also be present when hazardous tests are being performed.

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3. Hold-Harmless Agreements

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Situations may arise, of course, where the Government will be liable to contractor employees, but, if so, the Government should not attempt to contract out of its liability, The same principle applies to requiring insurance carriers to waive their right of subrogation against the Government.

Instead of attempting to limit Governmental liability, the question now being studied is whether the Government should indemnify contractors against the risks of catastrophic accidents resulting from its programs or otherwise assume the risks of such accidents. The trend seems to be toward the Government's assuming a larger share of the risk arising from its programs, rather than toward a lessening of Governmental liability.

It may be that these rather general observations do not answer the specific question you had in mind. If not, or if you desire more advice on a particular aspect of the problem, please let us know, and we will be happy to give further assistance.

"orig sgd by"

Paul G. Dembling
Deputy General Counsel

AG/RLH

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F-139

APPENDIX # 3
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NASA - Ames

Moffett Field, California
June 6, 1966

MEMORANDUM for Chief, Simulation Sciences Division

Subject: Medical Safety for Motion Simulators

1. With reference to our informal discussions on this subject, I have enclosed several pertinent articles concerning guidelines and recommended procedures for the handling of human subjects as volunteers for experimental procedures at Ames. In general, I think these comments are pertinent and acceptable; the central structure of these recommendations is based on adopted and presently used proposals by the Army and University of Illinois concerning the use of volunteers as subjects of research. I would recommend that a proposal similar to that drawn up by Dr. John Greenleaf be formulated jointly by the senior medical officer in your Division, you and me, and then submitted to the Director.

2. I recommend that both engineering and medical guidelines be formally drawn up for all simulators which will carry humans. Such a syllabus would formally summarize the previous experience at Ames when humans have been used as test subjects and would act as a rough reference for judging future proposed programs on these simulators. Furthermore, such guidelines would also be useful as a background upon which similar information from Brooks, Wright-Patterson, Manned Spacecraft Center or Johnsville could be judged. I do not feel that steady or sustained progress can be accomplished in this field if such guidelines are not available. To date, each problem has been handled individually without amassing a documented history of past performance. Lastly, it will be necessary to have these pieces of information to train future physicians as medical monitors.

3. As the Life Sciences program continues to grow and attract investigators, the number and caliber of proposed experiments involving human subjects on the motion simulators will increase. It is to be expected that proposed experiments will increase in complexity since many physiologic experiments have been conducted on centrifuges over the past 30 years, with the result that many of the easy or simple tests have already been accomplished. Since Ames will own one of the most modern and sophisticated simulators in the history of this research area, it should be clear that mechanisms must be set up within Ames to satisfy medical-legal responsibilities for presently proposed experiments, but, more importantly, for experiments proposed in the near and distant future. I cannot stress too strongly that whatever the mechanism is for satisfying these needs, it should also allow freedom for the investigator. Absolute safety cannot be the

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sole objective in these cases if these devices are to be used for experimentation. Some compromise must be reached in each case between the risks involved and the objectives to be gained. I do not agree with the suggestion put forward by Mr. George Holden in his memorandum to the Director dated May 23, 1966, for placing the responsibility of deciding the criteria for medical safety in the hands of an outside group. I feel that this must be done by a competent group in-house, preferably by those investigators who have had previous experience in these areas (I recommend Dr. John Billingham and myself in this regard) or have been senior investigators for programs using these devices. It would be logical and acceptable to have the individuals mentioned in Item 5 of Mr. Holden's memorandum review or comment on a joint proposal for medical safety criteria written by the Biotechnology and Simulation Sciences Divisions. Comments, recommendations or suggestions from the proposed reviewing board could then be incorporated, modified or deleted from the original safety proposal by the Medical Advisory Board.

4. I would like also to recommend and comment on the individuals appointed to the Medical Advisory Board. The duties and responsibilities of this Board must be clearly stated. The Board should serve the dual purpose of defining the medical-legal responsibilities of this Center for human volunteers as subjects for research and of defining the medical safety criteria and procedures to be used by all investigators and medical monitors when using human test subjects. Aside from legal representation, this committee must contain individuals with specialized and personal experience in clinical research. A Ph.D. degree does not satisfy medical-legal requirements. Only M.D.'s with at least two years of clinical experience and, preferably those individuals with personal experience with motion simulators, should be chosen. The Board should include at least three M.D.'s of this caliber and be sufficiently flexible to include or replace appointed individuals by personnel with more depth of experience when the occasion arises.

5. Finally, I would like to suggest that the following subjects be covered on the syllabus on medical safety:

a. Introduction - past history of divergence from medically safe procedures, and AGARD biodynamics committee recommendations on criteria for acceleration and safety.

b. Past history of medical safety and monitoring at Ames.

c. Guidelines for using humans as subjects for research, consent forms, pre- and post-run examinations, criteria for selection of medical monitors, duties of medical monitors, etc.

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d. Criteria of engineering safety.

e. General procedures for judging a proposed experiment as acceptable or not acceptable. When should medical monitor be used? When is an experiment considered hazardous?

f. Functions of Medical Advisory Board, its structure, and procedures.

g. What medical equipment should be available, instruments and drugs? Where should they be located? Who cares for them?

h. Detailed list of possible types of emergencies and procedures for handling each type.

6. I would welcome the opportunity for further discussions on these matters. I'd like to see an agreed system get off the grpund as soon as possible.

SEB/mdf
JJBJB
HS:kn

Harold Sandler
Environmental Control Research Branch
Biotechnology Division

Enc. 1. J. E. Greenleaf memo to S. E. Belsley, Mar. 26, 1965 (copy)
2. Draft Report from ad hoc Committee on exper. use of human subjects, 7/63
3. Med. Ethics: Brit. Unit Offers Guidelines for Research Involving Human Subjects, Science, 145:1024, 1964
4. Human Experimentation (A Review - abstract), Hartman, F. W., M.D.
5. Principles of Safety Monitoring of Research on Accel. Utilizing Human Subjects, Hiatt, E. P., M.D.

ENCLOSURES RETAINED IN BIOTECHNOLOGY DIV. FILES

cc: Mr. S. E. Belsley
Dr. John Billingham

Principal decision that no appropriated funds may be expended for insurance premiums is in 19 Comp Dec 798.

APPENDIX #4

July 15, 1966

AMES LEGAL MEMORANDUM 1-66

SUBJECT: Use of motion simulation devices at Ames for controlled human research

In his memorandum of June 6, 1966 to the Chief, Simulation Sciences Division, Mr. Harold Sandler of the Biotechnology Division pointed out inter-alia that-

> "As the Life Sciences program continues to grow and attract investigators, the number and caliber of proposed experiments involving human subjects on the motion simulators will increase. It is to be expected that proposed experiments will increase in complexity since many physiologic experiments have been conducted on centrifuges over the past 30 years, with the result that many of the easy or simple tests have already been accomplished. Since Ames will own one of the most modern and sophisticated simulators in the history of this research area, it should be clear that mechanisms must be set up within Ames to satisfy medical-legal responsibilities for presently proposed experiments, but, more importantly, for experiments proposed in the near and distant future."

At a meeting convened by the Director of Ames on June 17 ultimo, concern was expressed that advanced research in motion simulation--perhaps in new and relatively untried areas of investigation--may increase, perhaps unavoidably, the array and degree of hazard to the human subject. If the study conducted by Fraser[1/] is apposite in describing the type and quality of research to be undertaken at Ames, then even a lay comprehension of the study, points to possibilities through misadventure of serious injury to the

subject. As a consequence obvious questions of tort liability emerge but apart from those questions there exist the less obvious, but perhaps more important, problems of "preventive law" involving the discernment of ethical and juridical standards which govern controlled human research. Before discussing those standards as well as apparent questions pertaining to tort liability, it may be useful to explore the distinctions made by legal commentators between "experimentation" and "human research."

1. Differentiation between "experimentation" and "human research"

While the courts have not sought to strike meaningful distinctions between "experimentation" and "human research," the former term has been considered in the narrow milieu of the physician's care and concern for his patient, and, in this limited context, falls within the realm of malpractice if such care and concern are wanting.[2] Landmark cases in the law are regrettably confined to this concept of "experimentation," and as a result the use of this term, according to legal commentators, has been obscured, if not misconstrued, by the courts for the past two centuries.[3] In contradistinction to the case law concept of "experimentation," "human research" comprehends an investigation or observation by a professionally trained biological or medical scientist on, or involving the use of, human beings healthy or ill primarily for the advancement of knowledge rather than for the benefit of a patient. Human Research, therefore, connotes the use of a human being as a subject rather than a patient.

Obvious legal implications flow from the distinction between "experimentation" and "human research." In formality of relationship the research situation usually calls for a more explicit, probably written, understanding between the parties. In the Doctor/Patient relationship, on the other hand, the patient usually accepts, within his experience, the conduct of the physician without expecting, or receiving, except for surgical or other procedures, a form evidencing consent or waiver.[4]

To the extent that differing implications exist between "experimentation" and "human research" coupled with the fact that the former term, from time to time, has been linked by the courts with ineptitude and misconduct by physicians and imposters, perhaps the term "experimentation" should be avoided where conveniently possible in the formulation by NASA of procedures and regulations governing use of manned motion simulation devices.

2. Protection of subjects in controlled human research

According to legal commentators, when the subject of physiological or psychological investigation is a "non-patient," the investigator enters areas covered by the "Nuremberg Code."[5/] Though formulated as a result of an ultimate in human depravity, the "Nuremberg Code for Permissible Human Experiments" remains today the most highly publicized and carefully developed set of precepts specifically drawn to meet the problem of controlled human research. Provisions of the Code are extensive and require no protracted discussion here.[6/] It is enough to conclude, however, that although this document forms no part of the statute law, a disregard by an investigator of the standards set forth in the Code would seem to be of substantial probative value in the assignment of criminal or civil liability by a court.[7/]

Presumably the procedures followed by Federal agencies for safeguarding the subjects of human research extend beyond the Nuremberg Code. In this connection there is attached in Tab A for study by Ames management the draft, of a proposed regulation by the U.S. Public Health Service for safeguarding subjects of clinical research. The comments of Mr. Edward J. Rourke, Assistant General Counsel, HEW accompany the proposed regulation. Parts of the draft may provide some basis for the formulation by NASA of agency-wide standards governing controlled human research. In view of the fact that controlled human research has been undertaken by NASA at other field installations in addition to Ames I submit that the formulation of procedures and standards for the protection of subjects should be instituted on an agency-wide basis.

3. Requirement for "Informed Consent" of the subject in controlled human research

The gravamen of the Nuremberg Code is the voluntary informed consent of the subject. As stated by the commentators--

> "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment."[8/]

While consent in any fully informed sense may not be obtainable in every situation it remains the goal toward which the investigator must strive for sociological, ethical, and clear-cut legal reasons.[9/] If the hazards of the research are not known to the investigator then this fact should be stated to the subject.

Cogent reasons for requiring a writing as evidence of the informed consent of a subject are contained in the comments of Mr. Edward J. Rourke, Assistant General Counsel, HEW (Tab A). With respect to written forms for evidencing consent there are attached in Tab B for study by Ames management, the drafts of specimen forms and accompanying instructions prepared by the Chief Counsel and others at the NASA-Manned Spacecraft Center for use at that installation. An adaptation of these instruments for use at Ames appears feasible. However, I do not recommend use of the "Short Form" as proposed for MSC, nor do I recommend that forms for Government employee subjects differ from those to be used by other persons. To the extent also that the enunciation of procedures governing controlled human research is of agency-wide interest, "consent forms" proposed for use at any NASA field installation should, in my opinion, be submitted to the General Counsel of NASA for study and approval.

Irrespective of any form which is devised or adopted, the document remains at best a statement which only evidences consent and understanding. It seems useful therefore to emphasize the admonition by commentators that--

> "Statements regarding consent are meaningless unless one knows how fully the /human subject/ was informed of all risks, and if these are not known, that fact should also be made clear. A far more dependable safeguard than consent is the presence of a truly responsible investigator."10/

4. Omissions from, and sufficiency of, "consent forms"

To comport with established NASA policy "consent forms" must not contain statements requiring the subject to waive, or otherwise release, rights against the Government, third parties, or individuals in the event of misadventure. This policy was disclosed to Ames management in a letter dated

April 5, 1961 from the NASA General Counsel to Mr. Arthur B. Freeman. In this letter the General Counsel asserted:

> "Since we are advised that the centrifuge tests are conducted in furtherance of the Government's approved space program, as a matter of policy, it would seem inappropriate to seek release of the Government at the expense of those participants who are contributing beneficially to the Government's program."

Apart from the interdictions of agency policy the type of waiver or release described above is, in my opinion, of doubtful legal validity.

With respect to the legal sufficiency of the "consent form," a failure by the research investigator to obtain from the subject informed consent based on full disclosure may result ironically in barring the uninformed subject from asserting a claim against the United States under the Federal Tort Claims Act. For example, if, in order to prevent undue fear or alarm, the investigator suppresses or withholds from the subject a fact necessary to form the basis of intelligent consent such suppression or withholding under the laws of California and certain other jurisdictions would doubtless fall within the purview of the statutory definition of "deceit."[11] Since under provisions of the Federal Tort Claims Act as set forth in 28 U.S.C. 2680 (h), a claim based on deceit or misrepresentation is not actionable against the United States[12] the injured subject might conceivably be denied the only adequate remedy at law for receiving compensation commensurate with the extent of his injuries. A similar unsound result might occur if, through lack of informed consent by the subject, the injuries which he sustained were construable under contemporary local standards as arising from a "battery" rather than through the negligence of an officer or employee of the United States.[13] I must conclude, therefore, that a well-conceived and sufficient statement evidencing the informed consent of the subject would inure as much to his benefit as it would to the scientific investigator and the Government.

5. Sanctions, remedies, and compensation

Discursive memoranda have been prepared by the NASA office of General Counsel and by the Office of Chief Counsel, NASA-Manned Spacecraft Center which respond to questions concerning civil liability, administrative settlement of claims, and the application of workmen's compensation laws in situations where, as here, controlled human research by NASA may prove hazardous to the human subject. These memoranda are contained in Tab C. To summarize portions of their contents:

a. Provisions of the Federal Employees Compensation Act, 5 U.S.C. 751 et seq. furnish an exclusive legal remedy with respect to officers and employees of the United States, other than military personnel, injured or killed in the performance of duty. Persons in the Armed Forces are covered by various military compensation acts which are also exclusive in terms of legal remedy provided.

b. Persons not within the ambit of the federal compensation acts as described above may sue the United States in tort for damages if the negligence of an officer or employee thereof caused, or contributed to, injury or wrongful death. With statutory exceptions not applicable here, the assertion, or recovery, of a claim against the United States under the FTCA does not bar the institution of suits against individual Government employees connected with the incident giving rise to litigation against the United States. A plaintiff, moreover, could sue the individual Government employee alone without choosing to sue the United States at all. Although the U.S. Department of Justice customarily provides counsel to defend suits against Government employees which arise from official actions in the course of employment, this accommodation by the Justice Department does not mean that a judgment against the individual employee involved may be paid by the United States.

c. Section 203 (b) (13) of the National Aeronautics and Space Act of 1958, as amended, 42 U.S.C. 2473, provides administrative authority for NASA to settle and pay claims not exceeding $5,000 for bodily injury or death, and provides also that NASA may recommend to Congress the payment of meritorious claims in any amount.

d. Employees of NASA contractors are protected by state workmen's compensation acts which provide statutory compensation for on-the-job injuries whether or not fatal. These statutes have been enacted by all States of the Union, and Congress has extended the application of these laws to territory within the confines of a State but under Federal jurisdiction.14/

Apart from the civil sanctions and remedies mentioned above, extraordinary sanctions including those of a penal nature might be exacted against the lax scientific investigator who is culpably negligent or wantonly reckless in the conduct of human research. Where criminal liability is at issue the informed consent of the subject, though obtained, would ordinarily be immaterial in averting prosecution.

For physicians involved as investigators or collaborators in controlled human research--including physicians employed by the Government--sanctions such as suspension or revocation of the license to practice medicine may be exacted by the authorizing State if there has been a failure by the physician to obtain the "informed consent of the subject." As disclosed in a recent proceeding in New York against two physicians,15/ the quality of the informed consent to be obtained is identical to the legal standard which has been discussed in preceding paragraphs. Thus, in suspending the physicians involved from practicing medicine, the New York licensing authorities asserted in the opinion of the case there considered that--

> "No consent is valid unless it is made by a person with legal and mental capacity to make it, and is based on a disclosure of all material facts. Any fact which might influence the giving or withholding of consent is material."

6. Miscellaneous

At the meeting convened on June 17 by the Ames Director the question was asked whether graduate university students, in addition to government and contract employees, may be used as "volunteers" in human research, the connotation of the word "volunteer" as meaning a person who provides services without compensation or other legal consideration. Although legal arguments may be made that the use by NASA of such services under the circumstances indicated would not constitute the acceptance of "voluntary services" within statutory prohibitions,16/ I recommend against the acceptance by Ames of the "voluntary services" described. Apart from receiving no compensation from the Government the graduate students here involved would probably not qualify as recipients under state workmen's compensation acts or federal compensation acts. In the event of their injury I perceive serious problems for the students and Government investigators alike in the absence of a suitable authorized contractual arrangement providing for the payment of money. In this connection a very recent decision by the Comptroller General (B-158690 of 26 April 1966) discloses that services from persons to be used in human research may be obtained through an "independent contractor relationship rather than an employer-employee relationship." In my opinion the negotiation by Ames of such a "non-personal services contract" should be with the University involved rather than with individual students.

In response to other questions which were raised, in my estimation liability against the Government and individuals would not vary or be affected materially if injury to a human subject were caused by the inept operation of, or

malfunction in, the test equipment rather than from hazards implicit in the nature of the experiment itself. If inherently defective test equipment were the proximate cause of injury then the subject might elect to sue the equipment manufacturer, but this election would in no way extinguish rights, otherwise available to him, to assert claims against the United States, individual Government employees, or both.

J. Henry Glazer

Footnotes

1. Fraser, Human Response to Sustained Acceleration NASA SP 103 (1966).

2. See Ladimer, "Socio-Medical-Legal Aspects of Human Experimentation" 3 J. Public Law 467, 472 (1954). See also Note in 40 Cal. L.R. 159 (1953).

3. See Ladimer, "Human Experimentation Mediocolegal Aspects," 257 New England J. of Medicine 18, 19 (1957). See also, Slater v. Baker, 95 Eng. Rep. 860 (1767); Carpenter v. Blake, 50 N.Y. 696 (1872); Fortner v. Koch, 261 N.W. 762 (1935).

4. Ladimer op. cit. supra note 2 at 484.

5. Freund "Ethical Problems in Human Experimentation," 273 New England J. of Medicine 687, 691 (1965).

6. Summarization of the ten principles enunciated in the Code can be found in Ladimer op. cit. supra note 2 at 488. See also Editorial entitled "The Ethics of Human Experimentation," 270 New England J. of Medicine 1014 (1964).

7. See discussion of criminal, tortious, and contract liability in Ladimer op. cit. supra note 2 at 499.

8. See Freund op. cit. supra note 5 at 691.

9. For a discussion of pitfalls in obtaining fully informed consent within the meaning of the Codes, see the excellent recent article by Beecher entitled "Ethics and Clinical Research," 274 New England J. of Medicine 1354 (1966).

10. Id. at 1355 (emphasis added).

11. In Section 1710 of the California Civil Code, "Deceit" is defined inter alia as "the suppression of a fact, by one who is bound to disclose it." See also, Salgo v. Leland Stanford, Jr., University Board of Trustees, 317 P.2d 170 (Cal. 1957).

12. See United States v. Neustadt, 366 U.S. 696 (1961); United States v. Gill, 156 F. Supp. 955 (1957).

13. See Moos v. United States, 225 F.2d 705 (1955).

14. See 40 U.S.C. 290.

15. Report of the New York Regents Committee on Discipline in the matter of Drs. Chester M. Southam and Emanuel E. Mandel, Docket Nos. 158, 159 (The University of the State of New York).

16. See 27 Comp. Gen. 194; 30 Op. Atty. Gen. 51.

C O P Y

Mr. Robert T. Hollinger
Legislative Legal Liaison Officer,

June 15, 1966

Edward J. Rourke
Assistant General Counsel

Research--Clinical--Conducted at PHS facilities--Proposed criteria PM-1000 PK-2000 PB-7000

We welcome the opportunity to review and comment on the proposed issuance by the Bureau of Medical Services (draft of May 6, 1966) of the policy to govern clinical research conducted at the Bureau's facilities. We have given special attention to paragraph 4 (b) of this draft, setting forth the criteria to guide PHS committees that will review proposed projects using human subjects, since what is being dealt with at this point are the conditions that bear directly on legal liability. Special attention is also due this portion since it is likely that the practices of the PHS in its own facilities will have considerable significance to institutions elsewhere that conduct clinical research with Federal grant support since they are governed by the same general policy of the Surgeon General.

As the result of our review we have prepared and attach a redraft of paragraph 4 (b) that we think covers all the elements covered in the draft of May 6 and in addition is in accord, with one exception, with the comments by Dr. De ashmutt dated May 12.

Regarding Dr. De ashmutt's comments, we agree with him that with the exception of minors and the mentally incompetent, personal benefit to the individual subject is not necessarily required if he freely chooses, upon full information, to "join the team" and participate in an investigation. We also agree that to require no "danger" to the subject at all is hardly realistic, and we know of no compelling legal reason why competent and informed individuals may not freely choose to undertake reasonable and limited risks for the benefit of medical research.

The one aspect which we have retained from the original draft, but which Dr. DeLashmutt questions, is the requirement that consent of the subject be in writing. We strongly urge its retention, not to replace the need for good oral understanding between subject and investigator, but because proof of consent is vital to the legal basis for the entire participation and proof of consent will be either difficult or impossible if there is no written consent signed by the subject.

In this connection, first, there is always the risk of misunderstanding of what was said and what the alleged consent covered. Second, recollections later (particularly where consequences take an unexpected turn) are notoriously unreliable even assuming the best intention. Finally, if the subject should die for any reason, testimony as to what was orally exchanged may not under many State laws be admissible at all, with the result that there will not be on the "record" any evidence of the subject's consent. In this posture, liability is practically automatic for any harm arising from the investigation.

We can assure you that written consent need not be a formidable obstacle. Well conceived projects require time to be developed and put into operation, and we doubt that any additional time will be required to prepare and execute a consent form. Although from a legal point of view the consent form should be explicit as to what is involved, we would certainly urge that, if this be considered not feasible, a summary consent form is better than none at all.

We will be glad of course to participate in any discussions of our redraft or of further developments.

Attachment

EJRourke:bb

cc: Mr. Willcox
Dr. Guthrie
Dr. Allen
Dr. Nilmar
Mr. Murtaugh

Bureau of Medical Services--Clinical Research Re Draft
(Attachment to memorandum 6/15/66 - Rourke to Hollinger)

4. . . .

b. The field and headquarters research committees shall take cognizance of the following criteria in their review of research proposals which involve human beings:

(1) The investigation must have an anticipated value or benefit to mankind that outweighs the risks involved to the human participants. In no event shall the investigation knowingly or deliberately involve undue physical or mental discomfort or the likelihood of death or of permanent injury or incapacity.

(2) Each human subject shall have a completely free choice to participate or not participate in any investigation and a free choice to terminate his participation at any time during the investigation.

(3) No human being should be accepted for any investigation unless:

(a) He has first been informed of the kind or nature of, and the reasons for, the treatment or procedures to which he will be subjected and of the known and possible hazards, disadvantages and

discomforts involved both during and following his participation; and

(b) His consent to participate is reduced to writing and is in such form as will indicate on its face that he has been fully informed of, and voluntarily accepts the risks involved.

(4) If the human subject is a patient who has been admitted for treatment by the Service, he shall not be permitted to participate in an investigation unless either:

(a) The investigational procedure has no relation to the illness for which he is under treatment and his participation will have no adverse effect on the course of his illness or its treatment either by interfering with, postponing, or any other way affecting, his progress and the standard or customary course of treatment; or

(b) The investigative procedure is intended and designed to improve the condition for which he is being treated and he is fully informed of his right either to reject or refuse the treatment or procedure under investigation and to receive

the standard or customary treatment, or to elect in writing to accept the treatment under investigation.

(5) No subject may participate in an investigative procedure unless:

(a) He is mentally competent and has sufficient mental and communicative capacity to understand his choice to participate; and

(b) He is 21 years of age or more, except that if the individual be less than 21, he may participate in a procedure intended and designed to protect or improve his personal health or otherwise for his personal benefit or advantage if the informed written consent of his parents or legal guardian be obtained as well as the written consent of the subject himself if he be mature enough to appreciate the nature of the procedure and the risks involved.

(6) Both appropriate staff and equipment resources must be available at the place the investigation is to be conducted to give all possible aid and treatment in the event the human subject suffers an accident or an adverse reaction while participating in, or as a consequence of, the investigation,

(7) The investigation must be conducted only by investigators qualified by scientific and medical training and experience to conduct the type of study involved and having the competence required to protect the well-being and safety of the subject; they and their subordinates assisting in the investigation must also be knowledgeable of the possible reactions and how to cope with them.

(8) Immediate reports of any untoward events harmful to participants and arising in the course of the investigation shall be made by the investigator to the review committee for the project involved; such committee shall retain responsibility to terminate any investigation if the risks developing appear to outweigh potential benefits or where, for any reason, further conduct of the investigation is not considered justified.

United States Government

M E M O R A N D U M

Date: November 18, 1965

TO : EA2/Manager of Systems Test and Evaluation
Attention: Mr. J. R. Baker

FROM : AL/Chief Counsel

SUBJECT: Test crewman forms

As requested, and after review of several forms suggested by interested MSC elements, we attach drafts of forms for the above purpose.

The longer form is based on the assumptions noted below, and will deserve modifications to the extent that these assumptions may not be correct. The clauses of the longer form are discussed first below.

Alternatives for modifications

1. On the back or reverse side of the form there is a "NOTE" of suggestions or instructions for use of the form, designed to serve as a convenient reminder of the requirements for its use. Whether such instructions are advisable probably depends chiefly upon the extent to which the requirements are spelled out in other rules and kept in mind by everyone concerned.

2. As drafted, the instructions, the form for employee signature, and the medical opinion statement are designed for multi-purpose use; i.e., to cover service in space environment simulation chambers, riding on the centrifuge, or work in or at other facilities where good physical condition is important or the hazards are somewhat unusual. This approach makes the papers as now written more lengthy, and it may be feasible to simplify them by limiting particular forms to simulation chambers or other particular facilities.

3. As worded, the papers undertake to cover exposure prior to specific work applications, e.g., exposures in training and practice. They also undertake to cover activities at other locations as well as at MSC.

4. The words used to identify the types of service to be performed should be scrutinized to assure that they are suitable for that purpose, when considered in light of any pertinent contract provisions, job descriptions or other definitive writings, and job assignments.

5. As now worded, there is a statement by the employee dealing with his own physical condition. This was included in case there may be substantial risk that a particular employee has become aware of some material physical condition subsequent to his last medical examination. It could also be included in case there are certain facilities for which a medical examination may not be required, but it would be desirable to know if the individual knows of any physical condition which might make his work in the particular facility unusually risky for him or for others.

6. The form includes a statement by the individual that he does not intend to release or waive any employee compensation or workman's compensation rights provided by his employer. Such a statement is not considered necessary so long as there is no question as to the service being within the course of and the scope of the employment; however, its inclusion may provide some reassurance to individuals signing the form.

7. The form does not incorporate any attempted waiver or release of rights against the Government, other third parties or individuals, in case of accident which may be thought to have been caused or contributed to by someone other than the injured individual. As you will recall, the factors against or favoring any such attempted waivers or releases have been explored and identified previously. Among the factors against were the Federal policy reflected in the Tort Claims Act, doubtful enforceability, etc.

8. It is assumed that in each instance the individual employee will have received any advisable preliminary instruction, training or practice before being permitted to work under the conditions of concern here, and that it might be well to have him indicate this and also be given an opportunity to ask any further questions before he signs the form.

Other points

In addition to the above points as to which some variation in the papers might be necessary or desirable, there are several additional points which we think should be reflected in the forms substantially as in the present drafts.

a. It would be highly desirable for the papers to reflect the decision or opinion of a supervisor to the effect that the activity of the employee is considered in the course and in the scope of his employment, in addition to also having the employee indicate his similar understanding. The supervisor rather than the employee is in the best position to decide this and to do it authoritatively, and as a matter of record. Of course there should not be anything inconsistent with this decision or conclusion in the pertinent job description of the individual.

b. There are potential disadvantages to use of the words "certified" or "certification" in this connection. According to our layman understanding, neither the medical expertise of the examining physician or the equipment and processes relied on in making the medical examination and reaching conclusions as to the results can ever assure against latent physical weaknesses or deficiencies, nor can the physician ever be assured that the individual being examined has remembered or disclosed all symptoms. If this is so, it may be illogical to have the physician "certify" that the individual is physically qualified for particular purposes. Instead, we feel it should be adequate and appropriate for the physician to indicate that a physical examination was given on a particular date, and give his expert opinion as to whether or not the individual is qualified for a particular activity. The physician should of course also have had an opportunity to know of the conditions to which the individual is likely to be exposed.

Somewhat similarly, it seems preferable for the supervisor to approve the work assignment for the employee, rather than to "certify" something about it. In general, it is best for a statement which is a matter of opinion or judgment to be expressed in the form of a conclusion, approval, or finding, rather than as a certification of fact.

c. As drafted, the papers may be suitable for use by contractor personnel as well as government employees. We have undertaken to include language at one or two points that appears consistent with both the Federal Employees Compensation Act and also the Workman's Compensation Act of the State of Texas. However, a contractor might conceivably have reason to prefer somewhat different language for use by his employees, and which might not be objectionable from a NASA standpoint.

d. A form prepared in the Personnel Division (Mr. E. R. Strickland) covered the supervisor's finding as to the work being within the scope of employment, and evidently anticipated that the form would be filed in the personnel folder along with the medical statement. If the employee form is to be used on a one-time basis, but the medical examination will be given at least annually, there is a question as to whether the medical statement should be on a separate piece of paper from the employee form, and whether the periodical medical statements should also be filed in the personnel folder.

Short Form

Also enclosed is a shorter form of a employee statement. This is based largely upon forms suggested by Dr. Hawkins, and another by Mr. Hinners and Mr. Stickland. Recognizing the desirability of having a form as succinct as feasible, we should consider whether this form is sufficient,

or would serve better if incorporating some or all of the longer form, based on the points and comments dealt with in paragraphs 1-8 and c. above. Several modifications have been added, based on points a. and b. above. As to Civil Service personnel at least, some conclusion is required as to whether the indication of "volunteer" should apply only to service as a test subject.

Please let us know of any further assistance that we might afford.

J. W. Ould

cc:
AC/Special Assistant to the Director
AH/Chief of Center Medical Programs
AM/Chief, Center Medical Office
AMS/Chief, Environmental Medicine
AM4/Chief, Occupational Medicine Branch
ES/Chief, Structures and Mechanics Division
EC4/Chief, Systems Test Branch
BP/Chief, Personnel Division, Attn: E.R. Strickland

AL:JWOuld:mh 11-18-65

I M P O R T A N T: Read reverse side before signing

_____
(Date)

I agree to participate in work in test facilities for human or equipment testing, or both, and evaluation of various types of spacecraft, life support and other systems, subsystems, components, experiments, or related equipment or facilities, at reduced atmospheric pressures and under simulated space conditions, in connection with my work at the NASA Manned Spacecraft Center, Houston, Texas. This includes service as a trainee, observer, operator, or otherwise as a test crewman as may be required; training and practice for tests; and service at facilities of the NASA/MSC Center and other Federal agencies, firms or institutions. I volunteer and agree to perform duties as a test subject as a part of my employment.

There has been explained to me and I understand the test operations and hazards involved; except as follows: _____
(if no exceptions, employee

_____.
should so state)

In making the foregoing statements I do not intend to release or waive any employee compensation or workmen's compensation rights provided by my employer.

To the best of my information, knowledge and belief I am in excellent health and physical condition and am not subject to any kind of heart disease, high blood pressure, or other ailment, except _____

_____
(List all; if none, so state)

Approved. Considered within the course of and scope of employment of the above individual.

_____
(Employee)

_____
(Date)

_____
(Chief, _____ Division, MSC)

or

_____
(Signature and title of supervisor, if contractor employee)

MEDICAL OPINION

Mr. _____, an employee of_____

_____, was given a physical examination

on _____and is / is not considered physically fit to perform duties, including preliminary training and practice and work, including duties as observer, operator, or otherwise as test crewman (Subject) for human testing and evaluation of equipment, facilities, components, or other items to be tested in facilities of NASA Manned Spacecraft Center at Houston, Texas, and comparable facilities of other Federal agencies or industrial firms, in connection with such duties in environmental simulation chambers at less than ambient pressure or riding on a centrifuge or _____.
(List other facility or equipment, if any)

_____
Chief, _____
NASA Manned Spacecraft Center

_____
(Date)

D R A F T

(For Reverse Side of Form)

NOTE: Individuals will not be permitted to perform duties inside of environmental simulation chambers at less than ambient atmospheric pressure, or ride on a centrifuge or work in _____ (List other facility or equipment, if any) _____, except on a voluntary basis, whether for purposes of training and practice or to perform any work, including that as subjects, observers, or operators; and will be subject to the safety procedures and requirements developed and implemented by MSC and required of all personnel in similar work.

Before an individual is permitted to sign the statement on reverse side, it should be ascertained that he has received instructions as to the operations and hazards involved and what he should or should not do for safety reasons, and has had any required practice or other training; and he should be given an opportunity to ask any further questions desired;

A medical examination, and medical opinion that the individual is considered physically qualified to participate in human testing and evaluation with the facilities or equipment to be used, dated within not more than one year from the date of such participation, is a minimum requirement in all cases.

United States Government

M E M O R A N D U M

To : C/Mr. Paul Dembling, Deputy General Counsel
NASA Headquarters

Date: June 20, 1966

From : AL/Chief Counsel
Manned Spacecraft Center

Subject: Legal aspects of hazardous experiments, etc.

Reference your memorandum of July 14, 1964, to me on the above subject. It was very useful.

Subsequently I undertook the identification of related problems, including attention to Texas law. The results were reflected in a draft memorandum of 6-10-65, copy enclosed. This was used for working purposes, although never completed in polished form. Advice on use of forms for employees was given locally in memorandum of November 18, 1965, copy enclosed.

A contractor's insurer was disinclined to cooperate, and the Government and its employees were not covered as additional insureds.

As the enclosures may be of possible interest elsewhere, copies are distributed as indicated below.

J. W. Ould

J. W. Ould

cc: w/enclosure

G/Mr. J. Henry Glazer, Office of General Counsel, NASA Hqs.
Mr. W. E. Guilian, Chief Counsel, Marshall Space Flight Center
Acting Chief Counsel, Lewis Research Center
Mr. Charles M. Kearney, Chief Counsel, Goddard Space Flight Center
Mr. John P. Lacy, Chief Counsel, John F. Kennedy Space Center
Chief Counsel, Langley Research Center

D R A F T
JWO:mh
6-10-65

MEMO

To : FA/Manager of Systems Tests and Evaluation

From : AL/Chief Counsel

Subject: Use of non-government personnel as test subjects or inside lock observers

Reference your memorandum of May 4, 1965, subject as above, concerning legal liability of specific individuals who will be directly associated with the test activity, such as the Medical Officer, test conductor and test director.

Since it is impossible to foresee all the possible combinations and variations in circumstances under which personnel might suffer injury or death due to malfunction of equipment or human action or inaction or other cause, or the subsequent circumstances as to treatment or assertion of legal liability claims, the comments below are unavoidably general in nature. If you will advise as to any particular points on which further advice may be desired, we will be glad to assist further. The footnote references are available if needed.

A. SUMMARY

(1) State Workmen's Compensation arrangements provide a standard of protection to contractor employees.

(2) For personal injuries during tests, the United States may be liable in "tort", if negligence of its employee caused or contributed to the injury.

(3) NASA has administrative authority to settle claims up to $5,000; and may recommend to Congress the payment of meritorious claims in any amount. Claims not settled may result in litigation and court decisions. - against NASA or US Govt?

(4) Defenses not available to the employer under Workmen's Compensation statutes may be available to others if factually supported; e.g., that the person injured was himself negligent; that the injury was caused

by a fellow servant; or that the injured person voluntarily assumed the risk of possible injury. Among the uncertainties on this are the novel status of a group of personnel of different employers working under a single test director and management.

(5) NASA employees conceivably could be faced with claims of damages for negligence, along with the Government; or conceivably, in litigation not including the Government.

(6) The Department of Justice customarily provides counsel to defend actions against Government employees based on official actions in the course of their employment. This does not guarantee payment of any judgment that might occur against the employee. However, since the Government would be interested, NASA might be able to use its settlement authority up to $5,000 before litigation, or recommend to Congress the settlement of a larger amount.

(7) Insurance carried by the contractor would afford substantial protection if feasible for the United States and its employees to be included as "additional assureds". In case no extra premium cost is borne by the Government from this, the extended insurance seems to offer the best protection available. If added premiums were called for, a problem arises since the Government customarily acts as its own insurer and statutory authority is needed for use of appropriated funds to pay for insurance in favor of the Government or its employees. Availability of no-extra-cost coverage should be investigated; if definitely unavailable, further attention will be directed at the problem. Study on the latter point will be continued.

(8) Having all individual participants sign acknowledgments of training and recognition of risks may deserve consideration primarily as a safety factor. It might also result in a basis for defense of claims by persons other than the contractor. However, some labor-management relations questions might occur. Other policy aspects may be involved.

(9) NASA medical personnel functions in connection with tests appear appropriate.

(10) The participation by any contractor should be within the scope of its contract work, and participation by any employee should be in the course of his employment. Otherwise, the protection of the State Workmen's Compensation Act may be unavailable to any of those concerned. Also, even if an employee initially "volunteers" for the test work under NASA management, his employer should give him explicit direction or instruction to perform service in this way.

(11) Corporate officers are not protected by the Texas Workmen's Compensation statute. If they were to participate, exceptional liability risks would therefore occur.

(12) Texas law would not necessarily be controlling in all instances, and comments here cannot be comprehensive as to all cases. For example, if contractor employees normally stationed in another state were temporarily assigned to the Houston Area for test purposes, other statutes or court decisions might become applicable to liability or compensation questions if such an employer were injured.

B. DISCUSSION

1. Contractors' insurance coverage; state workmen's compensation acts.

The employees of NASA contractors are protected by state workmen's compensation acts, which provide statutory compensation for on-the-job injuries. Such statutes have been enacted in all fifty states.[1] This includes Texas.[2] Congress has extended such state laws to include territory within a state but under exclusive Federal jurisdiction.

In most instances, the workmen's compensation acts, by their own terms, prohibit any attempts to obtain waivers or releases of the statutory benefits. Such prohibitions are valid. And even in the absence of express prohibition, attempted waivers have been held invalid as being against public policy.[1] The Texas statute invalidates waivers.[3]

From a policy standpoint, waivers might have the detrimental effect of discouraging participation in the tests. Also, if an accident were to occur, it could appear manifestly unfair for the burden of the risk to be borne solely by the injured individual.

Compliance by cost-type contractors with applicable workmen's compensation and occupational disease statutes is intended to be mandatory under NASA procurement policy. The advantages of general liability insurance for personal injuries or death are also recognized.[4]

It is important that all contractors concerned have adequate insurance arrangements. Also, it would seem advisable for control to be exercised to assure that employees do not expose themselves to test conditions otherwise than in the authorized course of their employment.

2. Potential liability of United States.

Under the Federal Tort Claims Act[5] Congress has provided for liability of the United States, in general, for damages caused by the negligence of

its employees while acting within the scope of their employment.

The protection afforded a contractor employee (or the personal representative or dependents of a deceased employee) from claiming damages from a third party whose negligence caused injury or death.[6] Under the Texas statute, a negligent third party may face a claim from either the injured employee or from the association which paid compensation to him, and the amount of the liability is not limited to the amount paid by the association to the employee.[7]

3. Methods of settlement of claims against United States.

NASA has authority under section 203(b)(13) of the Space Act to settle claims not exceeding $5,000 against the United States for bodily injury or death resulting from the conduct of the Administration's functions, and the authority to report meritorious claims over $5,000 to Congress for its consideration.

Claims not disposed of under section 203(b)(13) would ordinarily be tried in a Federal court, with Department of Justice attorneys serving primarily as defense trial counsel.

As with respect to litigation in other matters, claims and litigation are sometimes settled prior to final court decisions where the questions of liability or amount of damages are uncertain and a reasonable compromise is feasible; however, it is not within the discretion of NASA to settle claims in litigation or in excess of $5,000.

4. Possible defenses by United States.

A third party against whom an employee's claim is asserted may offer certain defenses, when supported by the facts, that are not ordinarily available to the employer himself in a proceeding against him under the workmen's compensation statute.

These are: that the employee was guilty of contributory negligence; that the injury was caused by the negligence of a fellow employee; and that the employee had assumed the risk of the injury incident to his employment. The "fellow employee" would be someone else employed by the same employer, and ordinarily not an employee of some other contractor.

For the United States to be held liable at all and without regard to any defenses it might have, it would be necessary for the complaining person to show that negligence on the part of a NASA employee has caused the injury (except perhaps in strict or absolute liability situations).

The question would then arise whether the defenses mentioned above are available to the United States. It seems probable one or more would be, in substance, regardless of whether the test arrangements constitute a temporary cooperative agreement or joint venture between the Government and contractor; however, the "loaned employee" doctrine might be applied, in which case the Fed. Emp. Comp. Act presumably would apply and fix liability of the United States under it.

5. Potential liability of NASA employees.

In Texas, as in other states, an employer is responsible to third persons for damages due to negligent acts of an employee done in the course of his employment; and the employee is also responsible to the third party for his own lack of care or other wrongful act.[8] The Texas Compensation Act would not prevent a contractor employee from making a claim against the United States or a MSC employee on account of their negligence in causing him an injury.

Generally, in Texas, a supervisory employee is not liable to a third person for the negligence of a competent subordinate in which he did not participate, the subordinate being the employee of the employer and not of the superior officer.[9]

Ordinarily, in Texas, the liability of both employer and his negligent employee may be enforced in a joint proceeding in court against both the negligent employee and the employer; e.g., the United States. The employee is not immune from an action against himself alone if for some reason the injured person should choose to bring suit against him alone. The more usual practice is to bring suit against both employer and employee, or against the employer alone.

Only with respect to motor vehicle accidents by employees, while acting within the scope of their employment, has Congress taken action to exonerate the employee from liability by making the suit against the United States the exclusive remedy (provided certain procedures are followed by the individual against whom suit is brought).

In test procedures it is not inconceivable that suit could be sustained against an employee but with the United States not being also a defendent, even though the employee was acting within the course of his employment.[20]

The Federal Tort Claims Act does not cover every possible basis for claims. It excludes, for example, suit against the United States where a claim is based on performance or non-performance of "a discretionary function or duty ...". What this term covers is very poorly defined by court decisions, and there is no statutory definition.[10] There are other exclusions, but these do not seem relevant to the subject.

If a judgment is entered against the United States and paid by it, the Government cannot require the employee to reimburse (indemnify) it.[19] Neither could the claimant require dual payment by the employee.

It should be noted that the potential liability of a negligent Federal employee is somewhat different where the injured person is a fellow Federal employee. The Federal Employees Compensation Act has been interpreted as not precluding a claim and litigation in such a situation.[20, 28] One reported case was against three Air Force medical officers and a civilian doctor employed by the Air Force, claiming damages for injury from negligent surgery. Another case involved a motor vehicle collision. Unlike the Texas Compensation Act, the Federal Act does not include any provision making the rights to compensation under the statute the sole remedy as to fellow employees. This leaves the way open for a claim based on negligence.

6. Defense of Government employees; special statutory relief.

It is currently the general practice of the Department of Justice to provide counsel and representation to Government employees where the interests of the United States would be jeopardized should the suits be undefended and as a result the United States might itself become liable "in tort" or otherwise for damages arising out of the employees action.[11]

That practice does not include the actual payment by it of any judgment that might result in a suit brought against the employee alone. Neither does it appear that, if an employee were for some reason to hire his own private attorney to defend or settle a case, he could expect any support from the Comptroller General for an allowance by Congress to cover his expenses.[12]

As noted above, however, NASA does have certain limited authorities under Section 203(b)(13) of the Space Act, and it is conceivable that situations might arise where NASA could use such settlement or other authority in connection with claims arising from a hazardous experiment, although not including payment of private counsel fees or settlements by it of more than $5,000.

Defenses that the United States might assert should also be available to its employees in suits against them by a contractor employee; e.g., contributory negligence, negligence of a fellow employee, assumption of risk, dependent upon the circumstances.

7. Possible extension of contractor insurance to Government.

Although it is difficult to find a solid basis for any extra expense to the Government, the inclusion in the contractors' insurance of the United States, its agents, servants and employees acting within the scope of their authority, as additional assureds, would provide further protection to NASA employees. Inclusion of Government employees alone might be feasible.[27]

If this coverage could be accomplished without payment by the contractor of an additional premium at the ultimate cost of the Government, it would seem to be the best available solution. Expenditures of any extra premiums for the coverage may be subject to challenge or disallowance, although arguments could be advanced in defense of the action. To date no rulings have been found in favor.[13] Exploration of the feasibility of the coverage without extra premium through appropriate channels would appear preferable in advance of further effort to justify extra premiums, which may require express statutory authority since the Government customarily acts as self-insurer.

Waiver of subrogation rights by insurers as to the Government, its agents, servants and employees, would be desirable in any event. Also, consider the feasibility of an agreement by the insurer not to plead the defense of loaned or special Government employee or the equivalent without written consent of the Government. The Government might wish to give such consent if itself liable, either at law or under the Federal Employees Compensation Act. So also as to the defense of sovereign immunity.

8. Promoting safety and hazards knowledge.

Several advantages could result from a practice of having test participants sign a written acknowledgment, prior to conduct of any hazardous test operation, stating among other things that they have had

fully explained to them and understand the test operations and hazards involved and voluntarily wish to participate under the test conditions.[22] This would include clarification that no workmen or employee compensation rights provided by the employer are waived.

It is understood that the intent is to instruct all participants carefully in advance as to what they should or should not do for safety reasons, with practice or other training reasonably necessary.

Signing the acknowledgment could serve as a reminder to ask any further questions desired. Also, if any proposed participant has for any reason failed to receive the advance instruction, the acknowledgment should help to identify this fact before it is too late.

Some management-labor relations questions might occur, and other policy aspects may be involved.

9. NASA medical personnel.

The Texas Workmen's Compensation Act provides that an employer having a regularly paid physician to administer to or treat injured employees shall file with the State Board the physician's name and a copy of the contract of employment, indicating fully the extent and scope of the employment and compensation paid. If not done, injured employees may obtain medical and hospital services and medicine elsewhere. The employer must notify employees, at or before the time of injury, what physicians have been arranged for by contract. This statute also appears to have some significance as to the binding nature of statements made by the physician; however, the full objectives of the statute have not been determined.

As to military medical personnel detailed to NASA by the Armed Services, there appear to be no regulations which would prohibit them from participating in scientific tests or research activities; the only possible restriction mentioned would be against giving general medical treatment to contractor employees (aside from first aid and emergency care).

Federal agencies have authority to provide programs for health services to their own employees after consultation with the Public Health Service.[13] NASA has special statutory authority to cooperate with others in the use of services, equipment and facilities.[14] It has authority for planning, directing and conducting aeronautical and space activities, so there can be no doubt of its authority to conduct experiments relating to man's capacity for space flight and to utilize the services of scientific and medical specialists in that connection.[1]

It is assumed that the contractors will maintain their own normal occupational medical services for their own employees, except to the extent that test objectives and conditions require provision directly by NASA. This matter, however, may involve questions beyond those of liability being considered here, so that no opinion is expressed on the matter.

10. Participation should be within contract work and course of employment

For workmen's compensation protection to be available, the contractor employee must be acting "in the course of his employment" at the time of an injury. This means that his activity should be within the scope of the contract work which the contractor is performing.

There is a possibility that, even under those conditions, the statute might be held inapplicable. For example, there are precedents in Texas as in other states, to the effect that an employee whose services are loaned to another becomes temporarily the employee of the other for various purposes of the employer-employee relationship.[15] This is sometimes referred to as the "loaned" employee or servant doctrine. No Texas statute or reported court decision has been found that either applies or rejects the doctrine with respect to the State Workmen's Compensation Act, without ambiguity.

There is also the possibility, as noted above, that a contractor employee participating under the direction and control of NASA representatives would be considered within the definition of "employee" under the Federal Employees Compensation Act.[16] Also, under the Federal Tort Claims Act.[21]

Both the State and Federal statutes are normally subject to liberal construction, so that it seems highly unlikely an individual performing in accordance with instructions from his regular ("general") employer and those rules fixed by MSC and instructions from the authorized MSC test managers would ever be excluded under both statutes. If he were, the "common law" rights would still be available subject to any applicable contractual commitments.

More particularly, however, the definition of "employee" under the Texas statute appears to avoid any exclusion of a loaned employee from protection since it includes an individual who is employed in the usual course of the trade, business, profession or occupation of the employer and who is temporarily directed or instructed by his employer to perform services outside of the usual course of trade, etc., of the employer.[17]

APPENDIX #5
P. 82

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
WASHINGTON, D.C. 20546

IN REPLY REFER TO:

September 30, 1966

Mr. J. Henry Glazer, Esq.
Ames Research Center
Moffett Field, California 94035

Dear Jack:

Here are a miscellaneous group of some of the forms we were talking about. Warren Stolusky's draft of an NMI and forms is not included, but I will send you a copy as soon as we get one into legible form.

Regards,

Stephen J. Gross
Office of General Counsel

Enclosures

P. 83

NMRI FORM 3 (6-63)

NAVAL MEDICAL RESEARCH INSTITUTE
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND

CONSENT TO VOLUNTARILY PARTICIPATE IN RESEARCH EXPERIMENT

DATE _____

I hereby volunteer to participate, as a test subject, in a research subtask being conducted by the Naval Medical Research Institute entitled:

Project ARGUS (Advanced Research on Groups Under Stress), Neuropsychiatric Factors in Performance Effectiveness for Future Weapons Systems Crews,

the experimental design of which has been approved by the Chief, Bureau of Medicine and Surgery and use of human volunteers approved by the Secretary of the Navy. The nature and purpose of the procedures have been explained to me. I understand that the procedures are experimental and that my consent to participate does not constitute a release from any possible future liability by the Navy attributable to the experiments.

SIGNED: _____

_____
(TYPED NAME, RANK, RATE, OR GRADE)

WITNESSED: _____

Copy to:
Service Record, jacket or personnel file

(Short Form - Crew Systems)

_____
(Date)

I, _____, hereby volunteer to serve as a test subject; observer; operator or otherwise as test crewman for human testing and evaluation of various life support systems, subsystems, and components being tested in facilities of the Manned Spacecraft Center and other Federal agencies and/or at industrial firms, including tests at reduced atmospheric pressures and under simulated space conditions.

I understand that my participation in these tests is considered a part of the duties of my employment.

_____
(Employee)

Approved: _____ _____
(Chief, _____ Division) (Date)

AIR FORCE REGULATION
NO. 169-8

DEPARTMENT OF THE AIR FORCE
Washington, 8 October 1965

Medical Education and Research

USE OF VOLUNTEERS IN AEROSPACE RESEARCH

This regulation establishes the policies and procedures for using human volunteers in aerospace research projects.

1. Application of This Regulation. The provisions of this regulation:

a. *Apply to:*

(1) Research, development, test, and evaluation (RDT&E) procedures that may result in distress, pain, damage to health, physical injury, or death of the subject. Such tests usually are conducted to determine either the level of human tolerance for a condition that may be imposed by Air Force operations or the adequacy of equipment designed for human use (see AFR 80-14).

(2) Investigations of disease, new treatment procedures, and drug research conducted by the USAF Medical Service for the benefit of patients.

b. *Do not apply to:*

(1) Any programs, tasks, and tests that involve inherent occupational hazards to health or exposure to potentially hazardous situations such as those encountered as a part of training or other normal duties, e.g., flight training, jump training, bailout studies, fire drills, gas drills, and handling of explosives.

(2) The human factors research portions of a research project when they involve normal training or other normal military duties and when disclosure of the research conditions would defeat the purpose of the investigation by revealing the artificial nature of the experimental conditions.

2. Voluntary Informed Consent. The voluntary informed consent of the human subject is absolutely essential.

a. The volunteer must have the legal capacity to give his consent and must give it freely.

b. Before a volunteer gives his consent he must be given an adequate explanation of the research study, i.e., its nature, duration, and purpose; the methods and means by which it will be conducted; and any foreseeable inconveniences, hazards, and effects on his health which could result from his participation in the experiment. The volunteer must also be told about any parts of the testing program which cannot be stopped or controlled by either the test subject or the person conducting the test.

c. The consent of the volunteer will be given in writing in the format shown by attachment 1. The volunteer must sign the consent in the presence of at least one witness who will then attest the volunteer's signature by signing in the place provided.

3. Principles, Policies, and Requirements for the Use of Volunteers in Hazardous Aerospace Research:

a. All essential preliminary tests with laboratory animals, dummies, and other human simulators must be conducted and evaluated before a human subject is used. Research on human volunteers will be conducted only to validate important results that are essential to a program.

b. Research studies using human volunteers will be so conducted that all unnecessary physical or mental suffering or injury is avoided. Such studies will not be conducted if there is reason to believe that disabling injury or death will probably occur. To this end, a physician will conduct and record the examinations he feels necessary before the test project begins.

c. The degree of risk to which a volunteer is exposed will never be more than is absolutely essential because of the urgency and importance of the solution of the problem that made the research project necessary.

d. The research project will be conducted by scientifically qualified persons; a physician will be responsible for the medical care of the volunteer. The physician or the principal investigator will have the authority to terminate the research study at any time.

e. The volunteer will be informed that:

(1) At any time during the course of

OPR: AFMSPA
DISTRIBUTION: S

the research project, he will have the right to revoke his consent and withdraw from the test without prejudice to himself.

(2) The principal investigator or attending physician may terminate the experiment at any time he considers it necessary, regardless of the volunteer's wishes.

4. Approval to Conduct Research Involving Volunteers:

a. *Action by Originating Laboratory.* The commander conducting the research will appoint a research committee composed of three scientists; the chairman must be a physician. Committee members will not include either the principal investigator or the physician responsible for the medical care of the volunteer during the experiment. This committee must review and approve or disapprove all proposed RDT&E protocols that will require use of human volunteers.

b. *Action by the Surgeon General.* No research using volunteers will be undertaken without prior review and clearance by the Surgeon General. This will be accomplished by the submission of DD Forms 1498, "Research and Technology Review," through channels to the Surgeon General (AFMSPA). In no case will a project using human volunteers be initiated unless a DD Form 1498 has been approved by the Surgeon General. For urgent proposals to which DD Forms 1498 are not applicable, the Surgeon General's approval may be granted by telephone with confirmation by letter. Research projects performed under AFR 169–6 that involve human volunteers will be considered approved under the provisions of this regulation when letter approval by the Surgeon General is received. Research under AFR 169–6 need not be delayed pending submission and approval of DD Form 1498.

5. Publications Pertaining to Human Volunteers. All printed papers or articles that pertain to the use of human volunteers will contain the following footnote: "The voluntary informed consent of the subjects used in this research was obtained as required by AFR 169–8."

BY ORDER OF THE SECRETARY OF THE AIR FORCE

J. P. McCONNELL
General, U. S. Air Force
Chief of Staff

OFFICIAL

R. J. PUGH
Colonel, USAF
Director of Administrative Services

1 Attachment
Format for Volunteer Consent

P.87

(FORMAT FOR VOLUNTEER CONSENT)

Facility_____ Date_____

CONSENT OF HUMAN TEST SUBJECT

1. Having been fully advised of the dangerous nature and possible harmful consequences, I hereby volunteer to participate as a human test subject in the following experiment or series of experiments:

_____

(State nature of investigation, test, or experiment)

2. I further acknowledge that my consent has been freely given and that I have been informed that I may withdraw my consent at any time insofar as the nature or stage of the experiment permits.

_____

(Signature of test subject)

_____

(Witness)

I M P O R T A N T: Read reverse side before signing

_____
(Date)

I agree to participate in work in test facilities for human or equipment testing, or both, and evaluation of various types of spacecraft, life support and other systems, subsystems, components, experiments, or related equipment or facilities, at reduced atmospheric pressures and under simulated space conditions, in connection with my work at the NASA ~~Manned Spacecraft Center, Houston, Texas~~. This includes service as a trainee, observer, operator, or otherwise as a test crewman as may be required; training and practice for tests; and service at facilities of the NASA/MSC Center and other Federal agencies, firms or institutions. I volunteer and agree to perform duties as a test subject as a part of my employment.

There has been explained to me and I understand the test operations and hazards involved; except as follows: _____
(if no exceptions,

_____.
employee should so state)

In making the foregoing statements I do not intend to release or waive any employee compensation or workmen's compensation rights provided by my employer.

To the best of my information, knowledge and belief I am in excellent health and physical condition and am not subject to any kind of heart disease, high blood pressure, or other ailment, except _____

_____.
(List all; if none, so state)

Approved. Considered within the course of and scope of employment of the above individual

_____
(Employee)

_____
(Date)

_____
(Chief, _____ Division
MSC)

or

_____
(Signature and title of supervisor, if contractor employee)

MEDICAL OPINION

Mr. _____, an employee of _____

_____, was given a physical examination

on _____ and is / is not considered physically fit to perform duties, including preliminary training and practice and work, including duties as observer, operator, or otherwise as test crewman (Subject) for human testing and evaluation of equipment, facilities, components, or other items to be tested in facilities of NASA Manned Spacecraft Center at Houston, Texas, and comparable facilities of other Federal agencies or industrial firms, in connection with such duties in environmental simulation chambers at less than ambient pressure or riding on a centrifuge or _____.
(List other facility or equipment, if any)

_____
Chief, _____
NASA Manned Spacecraft Center

_____
(Date)

D R A F T

(For Reverse Side of Form)

NOTE: Individuals will not be permitted to perform duties inside of environmental simulation chambers at less than ambient atmospheric pressure, or ride on a centrifuge or work in _____ (List other facility or equipment, if any) _____, except on a voluntary basis, whether for purposes of training and practice or to perform any work, including that as subjects, observers, or operators; and will be subject to the safety procedures and requirements developed and implemented by MSC and (Name of Institution) required of all personnel in similar work.

Before an individual is permitted to sign the statement on reverse side, it should be ascertained that he has received instructions as to the operations and hazards involved and what he should or should not do for safety reasons, and has had any required practice or other training; and he should be given an opportunity to ask any further questions desired.

A medical examination, and medical opinion that the individual is considered physically qualified to participate in human testing and evaluation with the facilities or equipment to be used, dated within not more than one year from the date of such participation, is a minimum requirement in all cases.

Dec 16, 1966

NASA - Ames

HUMAN RESEARCH FORM OF CONSENT

1. The series of tests for which _____ is to
(Name of Subject)
serve as a subject have been explained to him in detail. The following information was included in this explanation:

A. TITLE - Critical Task Tester Evaluation

B. PURPOSE

To evaluate a Critical Task Tester (CTT) which is intended to provide a more sensitive index of stress than the usual tracking type test.

C. NATURE OF TESTS OR EXPERIMENTS

Four (4) men will operate the CTT at 2g to 6 g on the Five-Degree of Freedom Centrifuge. An additional vestibular stress will be introduced by imparting a slow pitching motion to the cab at 2g.

D. DURATION

The total test will last approximately three (3) consecutive weeks. Each subject will devote one to two hours daily for the first week, followed by four to five complete morning sessions extended over the last two-week period.

E. MANNER IN WHICH TEST OR EXPERIMENT WILL BE CONDUCTED

Four (4) male volunteers will be selected to participate in this experiment on the basis of their interest, motivation, and general health as determined by complete medical history and physical examination, including nystagmography. Each subject will spend approximately one week training with the CTT prior to centrifugation. The second week will provide the opportunity for graded exposure to centrifugation (EBI) while tracking and the third week will be reserved for actual testing. Test runs will last approximately five minutes at 2g and two minutes at 6 g if tolerated by the subjects. One of the subjects will have had prior experience of the centrifuge. Hourly wage for this work is $2.25 with a minimum of four hours allowed, including one hour travel time.

F. FORSEEABLE INCONVENIENCE, DISCOMFORT, AND/OR RISKS RELATED TO CENTRIFUGATION

1. Mechanical failure

2. Motion sickness

3. Pneumothorax

II. To be completed by subject

NOTE TO THE SUBJECT: READ PART I CAREFULLY. IF THERE IS ANYTHING IN PART I YOU DO NOT UNDERSTAND, ASK ONE OF THE SCIENTISTS OR TECHNICIANS WHO WILL BE CONDUCTING THE TEST OR EXPERIMENT FOR AN EXPLANATION

DO NOT SIGN THIS FORM UNTIL PART I HAS BEEN COMPLETED AND SIGNED.

(a) I hereby agree to participate, as a subject, in the tests or experiments described in Part I of this form.

(b) I am aware of the possible forseeable harmful consequences that may result from such participation, and that such participation may otherwise cause me inconvenience and discomfort.

(c) I acknowledge that my consent has been freely given and that I may withdraw my consent at any time.

The foregoing shall not be construed as a release of NASA from any future liability arising from or in connection with the tests or experiments in which I am to participate as a subject.

_____
Signature of Subject

_____
Date

APPENDIX #6

NASA-Ames
November 2, 1966

Assistant Director for Life
Sciences, 200-7

Chief Counsel, 200-11

Meeting of November 1 to consider proposed NASA Headquarters Management Instruction entitled "Human Research Policy and Procedures"

At the above meeting which you convened, paragraphs 1 through 7a of the proposed agency-wide Instruction were discussed. The remaining paragraphs are to be discussed at a meeting scheduled for 2:30 Monday November 7th.

Respecting paragraphs 1 through 7a the participants at the meeting were in accord that the "definitions" contained in the Instruction should be eliminated, and that no reference be made to the minimum age-limit for subjects. If there is insistence by NASA Headquarters management on the establishment of some minimum age limit, a minimum age of 18 might be acceptable. The participants agreed also that the proposed Instruction should extend to human research conducted by contractors and grantees of NASA and not be limited, as it now is, to research conducted "by NASA employees".

The participants agreed that paragraphs 1 through 7a be replaced with the following substantive revision:

MANAGEMENT INSTRUCTION

USE OF PERSONS IN AEROSPACE RESEARCH

1. PURPOSE AND APPLICATION

This Instruction enunciates policies and procedures relating to ~~controlled~~ human research with, or involving, persons as subjects. Applicable to NASA Headquarters and all field installations, this Instruction encompasses any human research conducted for, or on behalf of, NASA by officers and employees of the United States, or by contractors, or by grantees.

2. SCOPE

This Instruction extends to any research, development, test, experiment, or evaluation procedure which may expose a human subject to distress, pain, impairment to health, physical injury, or death. It does not extend to the use or employment of a trained professional person when knowingly following a recognized specialized calling or occupation which is clearly, or inherently, hazardous including by way of description and not limitation the callings of test pilots and astronauts. Nothing contained herein, however, shall be construed as authorizing the use or employment of any person for any purpose if there exists a likelihood that such use or employment will result in serious or permanent injury or death.

3. AUTHORITY

~~same~~ National Aeronautics & Space Act of 1958 as amended, 42 USC 2451

4. DEFINITIONS

eliminate

5. DETERMINATIONS

A. Prior to conducting human research a NASA official identified in subparagraph B hereof shall certify in writing -

a. that the particular individual(s) to be used as subject(s) for research ~~must be~~ appropriate for the type of research contemplated;

b. that all appropriate preliminary tests, including tests using laboratory animals, dummies, or other human simulators, have been conducted and evaluated;

c. that there is no basis for assuming the likelihood of serious, or permanent, injury to the human subject(s) involved nor shall any subject be exposed unnecessarily to physical pain or mental suffering;

d. that the inherent risks, if any, of the research proposed are warranted by the scientific or technological objectives to be gained.

B. NASA Officials who are authorized to make the certification identified in subparagraph A hereof are:

a. for NASA Headquarters _____;

b. for NASA field installations, the Director thereof. ~~The authority to certify may be delegated in writing by a~~ the Director ~~provided, however, that such delegation shall not extend to persons below the level of Assistant Director. The authority to certify may not be re-delegated~~. or his designee.

"Original signed by
J. Henry Glazer"

J. Henry Glazer

cc:
S. E. Belsley, 200-7
J. Billingham, 239-1
D. C. Brekke, 200-11
L. G. Bright, 200-2
E. Ogden, 239-8
R. M. Patton, 239-2
R. Pelligra, 210-7
G. A. Rathert, Jr., 210-7
H. Sandler, 239-4A
S. N. Stein, 200-9
A. Freeman, 200-13
JHGlazer:caw

P.97

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
WASHINGTON, D.C. 20546

IN REPLY REFER TO:

October 20, 1966

J. Henry Glazer, Esq.
Chief Counsel
Ames Research Center
Moffett Field, California

Dear Jack:

I am enclosing a copy of the initial draft of a proposed management instruction on "Human Research Policy and Procedures." The Director of Space Medicine, the Director of the Biotechnology and Human Research of OART, the Director of Occupational Medicine, and a number of other Chief Counsels are also getting copies but I thought you would be especially interested in the draft.

We await your comments.

Regards,

Stephen J. Gross
Office of General Counsel

P.98

DRAFT
S. J. Gross
W. G. Stolusky
10/19/66

MANAGEMENT INSTRUCTION

HUMAN RESEARCH POLICY AND PROCEDURES

1. PURPOSE

This Instruction sets forth policy and procedures relating to the conduct of human research.

2. APPLICABILITY

This Instruction is applicable to NASA Headquarters and all field installations.

3. SCOPE

This Instruction applies to all human research conducted [by NASA employees on behalf of NASA.] for NASA by Government investigators, contractors, and grantees

4. AUTHORITY

Section 203(b)(1) of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2473(b)(1)).

5. [DEFINITIONS] Scope of Instruction

As used in this Instruction:

a. "Human research" means any test or experiment in which a human subject may suffer stress, pain, damage to health, physical injury, personality or emotional disorder, or death.

The term does not include tests or experiments of which the only human subject is an astronaut or person selected for training as an astronaut.

b. "Subject" means a person ~~(man or woman)~~ whose performance is measured or who is otherwise observed in the course of a test and experiment.

6. INITIAL DETERMINATION CENTER DIRECTOR OR DESIGNEE

Prior to the conducting of human research, a determination in writing shall be made by a competent Government investigator, contractor, or Grantee institution that:

a. The importance of the objectives of the human research is in proportion to the inherent risk to the subject.

b. All appropriate tests, including tests using laboratory animals and other human simulators, have been conducted and evaluated and analyses of other relevant data have been made.

c. There is no reason to believe that serious or permanent injury is likely to occur as a result of such human research.

7. SUBJECTS

a. Only NASA employees over the age of 21 years may be subjects of human research.

b. No person may serve as a subject of human research prior to examination by a physician who, with knowledge of the nature of the contemplated human research, determines that such person is physically and emotionally qualified to serve as a subject of such human research. In instances in which it is expected that a significant danger to the subject will be emotional stress, the determination of the physician concerning the emotional qualifications of the subject shall be based upon the findings of a psychologist.?

c. No subject shall be asked to waive, nor shall anything herein be construed as a waiver by a subject of, any rights which may arise in connection with any stress, damage to health, physical injury, personality or emotional disorder, or death that may be suffered by the subject as a result of human research. Any instrument of waiver of the above executed by a subject, shall be deemed & construed by DOD as void ab initio.

d. No person may serve as a subject of human research until he has been fully apprised of the nature, purpose, and risks of such human research and has freely manifested his consent in accordance with paragraph 9 of this Instruction.

e. Subject always to subparagraph 7d, service as a subject of human research shall be considered a duty of the

subject, to be performed in accordance with the directions of the persons conducting the human research, until such subject withdraws his consent, in accordance with sub-paragraph 8c hereof, or until the human research is otherwise terminated.

f. No person shall serve as a subject of human research without prior approval of such service by the official in charge of the division in which such person is employed.

8. CONDUCT OF HUMAN RESEARCH

a. Human research may be conducted only by scientifically qualified persons acting under the direct supervision of a physician.

b. Human research will be so conducted that all unnecessary physical or emotional suffering or injury is avoided.

c. (i) At any time during the course of human research, the subject shall be free to revoke his consent, and withdraw from the test or experiment, and stop the experiment.

(ii) Any person conducting human research, or the supervising physician, must discontinue research if in his judgment it is likely, if continued, to result in serious injury to the subject.

9. VOLUNTARY INFORMED CONSENT

a. The freely given informed consent of the subject is essential.

b. Before a subject is permitted to give his consent, the contemplated human research must be explained to the subject, in language understandable to him. This explanation should include the nature, duration, and purpose of the human research, the manner in which it will be conducted, and all foreseeable inconveniences, discomforts, and/or risks to the subject which might result from the human research. If the nature of such inconveniences, discomforts or risks is not known beforehand, this fact should be made known to the subject.

c. The subject must be informed of any parts of the human research which cannot be stopped or controlled by either the subject or the person conducting the human research prior to the scheduled conclusion.

d. Subjects must give their consent in writing in such form as will indicate on its face that the subject has been fully informed of, and voluntarily accepts, the risks involved. See Attachment A for a suggested form of consent.

(Alternative 1)

HUMAN RESEARCH FORM OF CONSENT

Part I

I. To be completed by the person conducting the human research

In accordance with NMI , the tests human research or experiments, or series of tests or experiments, for which _____ is to serve as a subject has (name of subject) have been explained to him. The following information was included in this explanation:

(a) Nature of the tests-or-experiments research

(b) Duration

(c) Purpose

(d) Manner in which the research test-or-experiment will be conducted

(c) Foreseeable inconveniences, discomforts, and/or risks

Name and Title

Signature

II. To be completed by subject

NOTE TO THE SUBJECT: READ PART I CAREFULLY. IF THERE IS ANYTHING IN PART I YOU DO NOT UNDERSTAND, ASK ONE OF THE SCIENTISTS—OR TRAINED TECHNICIANS WHO WILL BE CONDUCTING THE ~~TEST OR EXPERIMENT~~ RESEARCH FOR AN EXPLANATION.

INVESTIGATORS

DO NOT SIGN THIS FORM UNTIL PART I HAS BEEN COMPLETED AND SIGNED.

(a) I hereby agree to participate, as a subject, in human research the ~~tests or experiments~~ described in Part I of this form.

(b) I am aware of the possible harmful consequences that may result from such participation, and that such participation may otherwise cause me inconvenience and discomfort.

(c) I acknowledge that my consent has been freely given and that I may withdraw my consent at any time.

The foregoing shall not be construed as a release of NASA from any future liability arising from or in connection with the tests or experiments in which I am to participate as a subject.

_____
Signature of Employee

_____
Date

Part III To be signed by the official in charge of division in which the above employee is employed.

The above employee, ordinarily employed in the division of which I am the official in charge, has requested that he be permitted to participate as a subject in the tests or experiments described in Part I of this form.

I hereby approve such participation, and direct such employee to report for duty to the persons conducting such tests or experiments.

_____
Name and Title

_____
Signature

(Alternative 2) Attachment A

HUMAN RESEARCH FORM OF CONSENT

Date

CONSENT OF HUMAN TEST SUBJECT

1. Having been fully advised of the dangerous nature and possible harmful consequences, I hereby volunteer to participate as a subject in the following tests or experiments, or series of tests or experiments.

_____

(State nature of tests or experiments)

2. I further acknowledge that my consent has been freely given and that I have been informed that I may withdraw my consent at any time.

3. My consent to participate as a subject shall not be construed as a release of NASA from any future liability which may arise from or in connection with the above tests or experiments.

_____

(Signature of subject)

Approved: _____

Name and Title
(to be signed by official in charge of division in which the above subject is ordinarily employed)

JH. Glazer, N-200-11

Mr Glazer
Pers. H.
OK

P. 107

NASA - Ames

Moffett Field, California
November 22, 1966

MEMORANDUM for Director

Subject: Human research utilizing Simulation Sciences Division man-carrying devices.

1. The Medical Services Branch (MSB) recognizes as its prime responsibility the safety of human volunteers participating in experiments which utilize man-carrying simulators, devices, or instruments assigned to the Simulation Sciences Division. Safety procedure extends beyond subject monitoring to include proper subject selection, complete pre- and post-test evaluation and provision for immediate emergency care in the event of a mishap.

2. The MSB will maintain an extensive file of volunteer test participants cross-indexed for age, occupation, simulator experience, altitude chamber experience, availability, etc., which will be accessible to any Ames investigator.

3. The type and extensiveness of the pre- and post-exposure medical evaluation will be determined in consultation with the principal investigator and in accordance with the complexity of the proposed experiment. Facilities for carrying out this evaluation are available through the Ames Dispensary.

4. Prior to testing, MSB will arrange a joint meeting of the principal investigators, the Legal Officer and test participants for the purpose of obtaining the informed consent of the latter.

5. The medical decision to terminate a test being conducted on an SSD man-carrying device will rest with a physician or physicians provided by the MSB. The test participant, principal investigator or computer operator may, of course, halt the experiment at an earlier moment, but may not, under any circumstances, defer the medical decision to terminate.

6. Finally, MSB recognizes the need for human research to advance the space sciences, and stresses that its intention is to facilitate and encourage the safe and productive use of human volunteers carried out in conformance with the highest moral, legal, and medical standards.

Ralph Pelligra

Ralph Pelligra, M.D.
Chief, Medical Services Branch

HJA
JFP
PGR
CAR
BP:dc

Copies to:
See attached distribution list

* § 130.37 Consent for use of investigational new drugs on humans; statement of policy.

(a) Section 505(i) of the act provides that regulations on use of investigational new drugs on human beings shall impose the condition that investigators "obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interest of such human beings."

(b) This means that the consent of such human beings (or the consent of their representatives) to whom investigational drugs are administered primarily for the accumulation of scientific knowledge, for such purposes as studying drug behavior, body processes, or the course of a disease, must be obtained in all cases and, in all but exceptional cases, the consent of patients under treatment with investigational drugs must be obtained.

(c) "Under treatment" applies when the administration of the investigational drug for either diagnostic or therapeutic purposes constitutes responsible medical judgment, taking into account the availability of other remedies or drugs and the individual circumstances pertaining to the person to whom the investigational drug is to be administered.

(d) "Exceptional cases," as used in paragraph (b) of this section, which exceptions are to be strictly applied, are cases where it is not feasible to obtain the patient's consent or the consent of his representative, or where, as a matter of professional judgment exercised in the best interest of a particular patient under the investigator's care, it would be contrary to that patient's welfare to obtain his consent.

(e) "Patient" means a person under treatment.

(f) "Not feasible" is limited to cases where the investigator is not capable of obtaining consent because of inability to communicate with the patient or his representative; for example, where the patient is in a coma or is otherwise incapable of giving informed consent, his representative cannot be reached, and it is imperative to administer the drug without delay.

(g) "Contrary to the best interests of such human beings" applies when the communication of information to obtain consent would seriously affect the patient's disease status and the physician has exercised a professional judgment that under the particular circumstances of this patient's case, the patient's best interests would suffer if consent were sought.

(h) "Consent" or "informed consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of an affirmative decision by such person the investigator should make known to him the nature, duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; all inconveniences and hazards reasonably to be expected, including the fact, where applicable, that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effects upon his health or person that may possibly come from the administration of the investigational drug. Said patient's consent shall be obtained in writing by the investigator.

Part II
#7
P. 169

NASA - Ames

Moffett Field, California
November 28, 1966

Memorandum for Assistant Director for Life Sciences, 200-7

Subject: Discussions at NASA Headquarters in connection with agency-wide instructions governing human research

Concerning the above, three days of meetings were held at Headquarters with representatives of the NASA General Counsel (Messrs Gross and Stolusky); a representative of the NASA Office of Manned Space Flight (Mr. Herbert S. Brownstein) and the Assistant Director of the Occupational Medical Division (a Dr. Estes). As a result of the meetings the proposed Headquarters Instruction of 20 October entitled "Human Research Policy and Procedures" has been replaced with the attached draft instruction entitled "Use of Persons in Aerospace Research". The attached draft instruction embodies the policies and approaches of Ames management. Specifically in this regard:

1. the Instruction extends to research performed by contractors and grantees of NASA as well as research performed "in-house", by Government officers and employees;

2. no minimum age for subjects is specified in the Instruction. The ARC approach, as proposed by the Life Sciences Division, is embodied in Paragraph 4A(a) of the draft;

3. authority for making "Determinations" within the meaning of Paragraph 4 of the Instruction may be delegated by an Installation Director;

4. the Instruction contains minimum agency-wide requirements. Respective NASA Installations will issue implementing directives which establish specific procedures keyed to the functional tasks of the Installation involved. Mr. Rathert's proposed memorandum, therefore, should be cast as an ARC directive which implements the Headquarters instruction.

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Except for Paragraph 8 which is a new provision, the attached draft instruction contains no substantive changes from the approaches agreed upon by Ames management. After certain minor editorial revisions are made, the attached draft will be circulated throughout NASA for coordination. Since several months will elapse before a final instruction is published by Headquarters, perhaps in the interim it would be advisable for Ames management to follow, as a matter of ARC policy, the procedures set forth in the attached instruction. In my opinion there is some immediate requirement for ARC to operate under such procedures at this time.

"Original signed by
J. Henry Glazer"

J. Henry Glazer
Chief Counsel

Enclosure:
draft instruction

cc:
S. E. Belsley, 200-7, w/encl
J. Billingham, 239-1, w/encl
D. G. Brekke, 200-11, w/encl
L. G. Bright, 200-2, w/encl
A. Freeman, 200-13, w/encl
E. Ogden, 239-8, w/encl
J. F. Parsons, 200-2, w/encl
R. M. Patton, 239-2, w/encl
R. Pelligra, 210-7, w/encl
G. A. Rathert, Jr., 210-7, w/encl
H. Sandler, 239-4A, w/encl
S. N. Stein, 200-9, w/encl

JHGlazer:caw

Prior follows
Management Instruction &
Consent form

P. 111

MANAGEMENT INSTRUCTION

USE OF PERSONS IN AEROSPACE RESEARCH

1. PURPOSE AND APPLICATION

This Instruction enunciates policies and procedures relating to human research with, or involving, persons as subjects. Applicable to NASA Headquarters and all field installations, this Instruction encompasses any human research conducted for, or on behalf of, NASA by officers and employees of the United States, or by contractors, or by grantees.

2. DEFINITION AND SCOPE

For the purpose of this Instruction "human research" means "any research, development, test, experiment, or evaluation procedure on man which may expose him to distress, pain, impairment to health, physical injury, or death." Neither this definition nor the scope of this Instruction extends to the use or employment of a trained person when knowingly following ~~this~~ a specialized calling or occupation which is generally recognized as hazardous including, by way of description and not limitation, the callings of test pilots and astronauts. Nothing contained herein, however, shall be construed as authorizing the use or employment of any person for any purpose if there exists a likelihood that such use or employment will result in serious or permanent injury or death.

3. AUTHORITY

National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2451 et. seq.)

4. DETERMINATIONS

A. Prior to conducting human research a NASA official identified in subparagraph B hereof shall certify in writing -

a. that with respect to age, sex, and other matters the particular individual(s) to be used as subject(s) for research are appropriate for the type of research contemplated;

b. that all appropriate preliminary tests, including tests using laboratory animals, dummies, or other human simulators, have been conducted and evaluated;

c. that there is no basis for assuming the likelihood of serious, or permanent, injury to the human subject(s) involved nor shall any subject be exposed unnecessarily to physical pain or mental suffering;

d. that the inherent risks, if any, of the research proposed are warranted by the scientific or technological objectives to be gained;

e. that the voluntary informed consent of each subject has been obtained in writing, consonant with the requirements contained in Paragraph 7 hereof.

B. NASA officials who are authorized to make the certification identified in subparagraph A hereof are:

a. for NASA Headquarters _____;

b. for NASA field installations, the Director thereof or his designee.

5. REQUIREMENTS FOR SUBJECTS

A. A subject of human research within the meaning of this Instruction shall be examined by a licensed physician who, with knowledge of the nature of the contemplated research, certifies that such person is medically qualified to serve as the subject thereof. At the conclusion of the test procedures, the subject shall be re-examined by a licensed physician.

B. No subject shall be asked to waive, nor shall anything herein be construed as a waiver by a subject of any rights which may arise in connection with any stress, damage to health, physical injury, personality or emotional disorder, or death that may be suffered by the subject as a result of research. Any instrument of waiver, if otherwise executed by a subject, shall be deemed and considered by the National Aeronautics and Space Administration as void ab initio.

C. No person may serve as a subject of human research until he has been fully apprised of the nature, purpose, and risks of such research and has freely manifested his consent in accordance with Paragraph 7 of this Instruction, and in no event may any person serve as a subject of human research

unless such person has legal capacity to give his voluntary informed consent.

D. No person may serve as a subject of human research unless he has first been provided personally with a copy of this Instruction and certifies in writing that he has read, and that he understands, this Instruction.

E. Service as a subject, if otherwise consistent with the foregoing provisions of this Paragraph, shall be considered a duty of the individual subject involved to be performed under the direction of the investigator conducting the human research unless, and until, such subject withdraws his consent in accordance with subparagraph 6C hereof, or until the research is otherwise terminated.

6. CONDUCT OF PROCEDURES

Human research within the meaning of this Instruction may be conducted -

A. Only by a responsible trained investigator who fully understands the nature, risks, and hazards of the research as well as the specific scientific objectives to be achieved.

B. Only if a licensed physician is immediately available at the situs of the research throughout the conduct thereof.

C. Only if the subject shall have freedom of action, at any point in the course of research, to revoke his consent, withdraw from the research, and terminate his participation

therein either temporarily or permanently: Provided, however, that for parts of the research which cannot be stopped or controlled by the investigator or subject, such research may proceed but only in strict consonance with the requirements set forth in Paragraph 7 hereof. The decision of the subject involved, or of the research investigator, or of the physician at situs to terminate, discontinue, and stop a human research procedure, or portion thereof, which is susceptible to control shall be obeyed without question and such decision shall be binding and conclusive.

7. VOLUNTARY INFORMED CONSENT

(Note to HQ revisor: No substantive comments except that an adaptation of the language in the Nuremberg Code might be preferable. This is an editorial matter.)

8. INTERPRETATION

Questions concerning the interpretation of this Instruction or scope of application thereof, shall be referred to counsel at NASA Headquarters or at field installations as appropriate.

(See Specimen Consent Form - Attachment A)

Attachment A

HUMAN RESEARCH FORM OF CONSENT

PART I

To be completed by the person conducting the human research

In accordance with NMI , the human research for which _____ is to serve as a subject
(name of subject)
has been explained to him. The following information was included in this explanation:

(a) Nature of the research

(b) Duration

(c) Purpose

(d) Manner in which the research will be conducted

(e) Foreseeable inconveniences, discomforts, or risks

_____
Name and Title

_____
Signature

PART II

To be completed by subject

INSTRUCTIONS TO SUBJECT: READ PART I CAREFULLY. IF THERE IS ANYTHING IN PART I YOU DO NOT UNDERSTAND, ASK ONE OF THE TRAINED INVESTIGATORS WHO WILL BE CONDUCTING THE RESEARCH FOR AN EXPLANATION.

DO NOT SIGN THIS FORM UNTIL PART I HAS BEEN COMPLETED AND SIGNED AND UNTIL YOU HAVE READ AND UNDERSTOOD THE NASA REGULATION (NMI _____) WHICH IS APPENDED TO THIS FORM.

a. I hereby agree, as a matter of my free choice, to participate, as a subject, in the human research explained to me as described in Part I of this Form.

b. I am aware of, and understand, the potential hazards, discomfort, inconvenience, and possible harmful results which I may experience from such participation and those which are foreseeable have been explained in detail to me by a trained investigator who will conduct the research, and, moreover, I am aware of the possibility that unforeseen hazards, discomfort, inconvenience, and harm to my person may ensue from my participation in the research.

c. I acknowledge that my consent has been freely given, that I may withdraw this consent at my sole election,

and that at any point in time I may stop the research from proceeding further except with respect to portions or aspects of the research beyond human control, and these have been explained to me fully.

d. I understand that the foregoing declaration by me shall in no way be construed as releasing NASA as well as any contractor or grantee thereof from liability arising from, or in connection with, the human research here involved.

e. I certify that I have read, and that I understand, NMI _____.

_____
Signature of Subject

_____
Date

PART III

Certification of Authorizing Official

Consonant with the requirements contained in NASA NMI _____ I, _____, hereby certify with respect to participation by _____ in the human research described herein that -

(a)

(b)

(c) (NOTE: The elements of certification are to be responsive to the determinations required in Paragraph 4 of the NMI)

(d)

(e)

Information Copy P.119 #8

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
NEGOTIATED CONTRACT

Contract No. NAS2-4397

ISSUING OFFICE

NAME	ADDRESS
National Aeronautics and Space Administration Ames Research Center	Moffett Field, California 94035

CONTRACTOR

NAME	ADDRESS
Massey Temporary Service, Inc.	480 Lytton Avenue Palo Alto, California 94301

CONTRACT FOR

Test Participants

NO MINIMUM in contract - ?

AMOUNT

Minimum $2,500.00
Not To Exceed Maximum $15,000.00

APPROPRIATION AND OTHER ADMINISTRATIVE DATA

RFP A-13236(DD-22)
Control Number FL001701C

Type of Contract: Time and Materials

Administration Cyt: National Aeronautics and Space Administration
Ames Research Center, Moffett Field, California 94035

Appropriation and Allotment Chargeable: 80X0108(67)

Priority Rating: N/A

Office to Make Payment: National Aeronautics and Space Administration
Ames Research Center, Moffett Field, California 94035

Security Classification: Unclassified

General Provisions: NASA Form 1334(November 1966)(Time and Material and Labor Hour Contracts) as revised by Article VIII is attached hereto and made a part of this contract.

DD:an

This negotiated contract is entered into pursuant to the provisions of 10 U.S.C. 2304 (a) (11) and any required Findings and Determination have been made.

THIS CONTRACT is entered into as of _____, 19 67, by and between the United States of America, hereinafter called the Government, represented by the Contracting Officer executing this contract, and Massey Temporary Service, Inc.

(i) a corporation organized and existing under the laws of the state of California

(ii) a partnership consisting of _____

(iii) an individual trading as _____

hereinafter called the Contractor. The parties hereto agree that the Contractor shall furnish and deliver all supplies and perform all the services set forth in the attached Schedule, for the consideration stated herein.

NASA FORM 457 (4/66)
37

FOR NASA USE ONLY: Project Engineer: Ralph Pelligra, M.D., N-243-1
Contract Administrator: Harold Mathews, N-241-1

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SCHEDULE

ARTICLE I

Statement of Work

The Contractor shall furnish all necessary services to provide test participants in accordance with the attached Statement of Work for Experiment Test Participants, RFP A-13236A, dated August 14, 1967.

ARTICLE II

Period of Performance

The contract period of performance shall be from date of execution by the Government until one year thereafter.

ARTICLE III

Consideration and Payment

A. Notwithstanding any other provisions of this contract, not more than TWO THOUSAND FIVE HUNDRED DOLLARS ($2,500.00) shall be expended without prior written authorization by the Contracting Officer.

B. The billing rates for test participants shall be as follows:

Degree of Risk (To be determined by the Technical Monitor and specified in Attachment A, "Human Research Consent Form")	Rate Per Hour
High	$6.75
Medium	5.41
Low	4.06

C. The Contractor agrees to provide additional test participant time during the period of performance, if so requested by the Contracting Officer and if additional funds become available and allotted to this contract. However, in no event will the total contract amount exceed FIFTEEN THOUSAND DOLLARS ($15,000.00).

D. Contractor's invoices shall be submitted in quadruplicate (an original and three copies) and shall be made out to the office designated to make payment, marked: "Attention, Fiscal Officer" and delivered to the Contracting Officer.

ARTICLE IV

Acceptance and Consent of Test Participants

A. Prior to conducting any testing, the Director of Ames Research Center or his designee shall certify to the acceptability and consent of test participants. Such certification shall be made in writing and include the following:

1. That with respect to age, sex, and other matters, the particular individual(s) to be used as subject(s) are appropriate for the type of research contemplated;

2. That all appropriate tests, including tests using laboratory animals, dummies, or other human simulators, have been conducted and evaluated;

3. That there is no basis for assuming the likelihood of serious or permanent injury to the human subject(s) involved, nor shall any subject be exposed unnecessarily to physical pain or mental suffering;

4. That the inherent risks, if any, of the proposed research are warranted by the scientific or technological objectives to be gained; and

5. That the informed consent of each test participant has been obtained.

B. For the informed consent of test participants to be obtained, as stated above, the following procedure shall be followed:

The Technical Monitor shall provide in detail the information called for by, and in the form of, Part I of "Human Research Consent Form," attached to this contract and made a part hereof, and referred to as "Attachment A." The Technical Monitor shall execute Part I of such form, and assure that such "Human Research Consent Form" is furnished to the test participant involved.

2. The test participant shall be asked to read both Part I and Part II of such "Human Research Consent Form." Part II thereof shall be in the form set forth in Attachment A. The Technical Monitor or a trained investigator designated by him, shall be available to answer any questions of the test participant.

3. Thereafter, if the test participant consents, he should so signify by executing Part II of the "Human Research Consent Form," which thereafter shall be transmitted to the Technical Monitor.

C. It is understood and agreed that the test participant's consent shall be entirely voluntary on his part.

ARTICLE V

Release of Information by Contractor

Information obtained from or developed under this contract shall not be released until approved by the Office of the Director, Ames Research Center. Proposed publicity releases (for public relations, advertising, or marketing) shall be coordinated with the Public Affairs Officer, Ames Research Center.

ARTICLE VI

Employees of and Responsibilities of the Contractor

A. The Contractor shall comply with all applicable Ames Research Center Regulations and procedures, including but not limited to the established working hours and closing for legal holidays.

B. The Contractor shall designate a representative authorized to receive and execute, on behalf of the Contractor, such notices and directions as the Contracting Officer may issue under the terms of this contract.

ARTICLE VII

Technical Monitor

The Technical Monitor will be designated by the Contracting Officer. Such designation may be changed or revoked at any time upon written notice to the Contractor from the Contracting Officer. The Technical Monitor will represent the Contracting Officer in the technical phases of the work. Any direction of the Technical Monitor to be valid: (1) Must be issued in writing consistent with the general scope of the work set forth in this contract; (2) may not constitute new assignment of work or change in the expressed terms, conditions or specifications incorporated into this contract; (3) shall not constitute a basis for any increase in the estimated contract cost or extension to the contract delivery schedule.

ARTICLE VIII

Alterations In Contract

The following alterations have been made in the provisions of this contract:

A. Form ARC 361 (May 67), Alterations to General Provisions and Form ARC 432 (5/1/67), Change to General Provisions are attached hereto and made part of this contract.

B. Form ARC 538 (Nov. 66), entitled "Changes" is added and Clause No. 3, entitled "Changes (June 1966)" in NASA Form 1334 (Nov. 1966) is deleted.

- - -

The rights and obligations of the parties to this contract shall be subject to and governed by the Schedule and the General Provisions. To the extent of any inconsistency between the Schedule or the General Provisions, and any specifications or other provisions which are made a part of this contract by reference or otherwise, the Schedule and the General Provisions shall control. To the extent of any inconsistency between the Schedule and the General Provisions, the Schedule shall control.

The Contractor represents that aggregate number of employees of the Contractor and its affiliates is: ☐ 500 or more, ☐ less than 500.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

THE UNITED STATES OF AMERICA

By _____
(Signature)

_____
(Contracting Officer)

CONTRACTOR

Massey Temporary Service, Inc.
(Name of Company or Individual)

By _____
(Signature)

_____
(Typed Name)

_____
(Title)

480 Lytton Avenue
Palo Alto, California 94301
(Address)

P.125

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

AMES RESEARCH CENTER

MOFFETT FIELD, CALIFORNIA 94035

STATEMENT OF WORK

FOR

EXPERIMENT TEST PARTICIPANTS

Statement of Work No. A-13236A August 14, 1967

I. SCOPE

The Contractor shall provide test participants for a series of experiments utilizing various man-carrying devices such as centrifuges, environmental chambers, rotating devices, treadmills, vibrational devices, airplane simulators, etc. The total number of participant hours will not be less than 500 or more than 3000 under this contract. Individual tests may last days, weeks, or months depending on the quality and quantity of data desired and obtained. Approximately four hours participation per day, two to five days per week, during the test period will be required from each participant. "In no event shall a test participant engage in testing under this contract for a period in excess of forty (40) hours per week without the prior written approval of the Contracting Officer, who may not delegate such authority." During the contract period, the Contractor will be expected to maintain a list of at least ten people who will be available upon two weeks notice for a given test. Regular attendance at all scheduled test sessions is required of a test participant.

A. Place of Performance - All tests will be performed either at the Ames Research Center, Moffett Field, California; at any test facility operated by the Government; or at an accredited medical facility, depending on the requirements of the specific experiment.

B. Medical Supervision - During test preparation and test operations, the participants will be under the direct medical supervision of a licensed physician acting as the Government Medical Monitor. The test participant will be provided with means to terminate any test for reasons of physical discomfort.

C. Subject Payment - Test participants shall be paid not less than the following, according to the degree of risk, as determined in advance by the Medical Monitor:

Low hazard tests	- $3.00 per hour
Medium hazard tests	- $4.00 per hour
High hazard tests	- $5.00 per hour

1. Minimum Test Period - A minimum test period of three hours shall be accredited to each test participant for each test session attended. Fractional parts of a test period, in excess of the minimum, shall be in increments of 15 minutes.

2. Payroll Preparation - The Contractor shall prepare all payroll forms, and the test participants shall be paid by the Contractor within 30 days of any test session.

D. Physical Examinations - Test participants shall pass a physical examination as specified by Government Medical Monitor prior to taking part in any testing. Upon completion of any testing, each participant shall submit to a second physical examination as specified by the Government Medical Monitor. These examinations will be performed at the Dispensary, Ames Research Center, Moffett Field, California. Any special medical examinations which cannot be performed at the Ames Dispensary will be performed at an accredited medical facility on written direction from the Technical Monitor and charged to the Contractor if funds are obligated for such purpose. Time spent for the purpose of taking physical examinations prior to the commencement of testing will not be reimbursable under this contract.

E. Travel - In the event that test participant travel (in excess of 50 miles from the Ames Research Center) is required in the performance of this contract, the Government, at its option, may provide transportation to the test locations. However, upon at least 48 hours notice by the Contracting Officer, the Contractor shall provide transportation and travel expenses for the test participants subject to reimbursement as follows:

1. Travel Costs - Contractor-provided transportation shall be reimbursed at the following rates:

   Actual Cost - Air, rail, or bus fare

   $0.08 per mile - Contractor private Auto.

2. Per Diem - Test participant travel expenses shall be reimbursed at the rate of $16.00 per day per employee for overnight travel, and at the rate of $4.00 per day for travel over 10 hours, but less than 24 hours.

F. Insurance - The Contractor shall procure and maintain workman's compensation that will cover each employee working under this contract, employer's liability, general liability, and auto liability insurance with a minimum limit of FIFTY THOUSAND DOLLARS ($50,000.00) per accident per individual. The Contractor shall be responsible for his insurance carrier(s) submitting a certificate of insurance to the Contracting Officer including a statement that the Contracting Officer will be notified in writing thirty (30) days prior to any cancellation or material change in the policies affecting the interests of the Government during the term of this contract.

II TEST PARTICIPANT QUALIFICATIONS

A. Age - 21 to 40 years

B. Citizenship - United States

C. Availability - Available for intermittent duty over contract period

D. Physical Examination - Capable of passing a physical examination as specified by the Medical Monitor.

E. Consent - The test participant will be required to execute a "Human Research Consent Form" as set forth in Attachment A, consonant with the procedures outlined in Article IV, of the contract.

Whereas the execution of such consent shall be entirely voluntary on the part of the test participant, nevertheless he cannot meet the qualifications for taking part in testing unless he does give such informed consent.

The form for consent and content of Attachment A which is incorporated as part of this Statement of Work is as follows:

ATTACHMENT A

HUMAN RESEARCH CONSENT FORM

PART I (to be completed by the Technical Monitor)

In accordance with NASA-Ames policy, the human research for which (Name of Subject) is to serve as a subject has been explained to him. The following information was included in this explanation:

(a) Nature of the research:

(b) Duration:

(c) Purpose:

(d) Manner in which the research will be conducted:

(e) Foreseeable inconveniences, discomforts, or risks.

(f) Degree of Risk (specify whether "High","Medium" or "Low").

____
Signature

____________ ____________________
Date Name and Title

- -

Part II (to be completed by test participant)

Instructions: Read Part I carefully. If there is anything in Part I which you do not understand, ask the Technical Monitor or a trained investigator designated by him for an explanation. NOTE: Do not sign this Part II until Part I above has been completed and signed by the Technical Monitor.

(a) I hereby agree to participate, as a subject, in the human research described in Part I of this form,

(b) I am aware of the possible harmful consequences that may result from such participation, and that such participation may otherwise cause me inconvenience and discomfort.

(c) I acknowledge that my consent has been freely given and that I may withdraw my consent at any time.

The foregoing shall not be construed as a release of NASA from any future liability arising from or in connection with the tests in which I am to participate as a subject.

Date

Signature of Test Participant

- - -

Rena H.

APPENDIX #9

NASA - Ames

Moffett Field, California
April 20, 1967

MEMORANDUM for Mr. Loren G. Bright
Executive Assistant to the Director, 200-2

From: J. Henry Glazer
Chief Counsel, 200-11

Subject: Draft proposal by Mr. George Rathert entitled: "General Administrative Procedure for the Ames Research Center Manned System Simulation Facilities"

The above proposal by Mr. Rathert must be considered within the context of a previous proposal for NASA-wide application which was cast, by ARC, in the form of an "NMI" and submitted for consideration and approval to NASA Headquarters. The proposed NMI generated at ARC, and approved by all elements of Ames including General Management, is entitled "Use of Persons in Aerospace Research" (hereinafter called the "agency-wide proposal"). To the extent, therefore that the "agency-wide proposal" represents the position of Ames General Management and is now undergoing consideration for approval at Headquarters level, it must be discerned whether the above draft by Mr. Rathert is consistent with the agency-wide proposal formulated, and espoused, by ARC.

Mr. Rathert's proposal is not consistent with the "agency-wide proposal" for the following reasons-

1. The agency-wide proposal contains a definition and scope of application for human research. The categorizations in the Rathert proposal based upon "degrees of risk" (viz: categories I, II, and II) are not valid tests for determining whether a given activity involving "human research" falls within the scope of the definition set forth in the agency-wide proposal.

2. The Rathert proposal should be cast as an implementation of the "agency-wide proposal" and

should be responsive to the information therein. Apart from leading the reader immediately to the agency-wide proposal, this approach would avoid redundancy and inconsistency. For example, paragraph 6 of the agency-wide proposal indicates that a "responsible trained investigator" and a "licensed physician" must be at the situs of the research. The Rathert proposal indicates in paragraph 1b(3) that "there must be at least two physicians involved". In a similar vein-

a. the documentation requirements in paragraph 4 of the Rathert proposal are inconsistent with paragraph 6 and attachment A to the agency-wide proposal

b. the functions of the "Medical Review Board" as set forth in the Rathert proposal (paragraph 3) are not responsive to the "Determinations" required under paragraph 4 of the agency-wide proposal

c. the selection of human subjects under paragraph 4 of the Rathert proposal appears to proceed independently of meeting the basic requirements for use and selection of subjects as set forth in paragraph 5 of the agency-wide proposal.

In addition to the above, the following comments and criticisms are offered:

3. Paragraph 3 of the Rathert proposal discloses that a "medical" review board will, among other things, approval or reject proposals to proceed with a given line of research. Why a "medical" review board? This departs from the "jury of peers" idea espoused in some of the literature concerning approval, "to go ahead", with a line of human research. The "Board" should be composed of laymen as well as scientists; this is not to say, however, that laymen should be in the majority. I believe that it would be a healthy system of "checks and balances" if one, or a couple of, laymen served on the board. And if a given line of "human experimentation" is simply at war with their "good common sense",

the laymen involved should vote against it notwithstanding "scientifically conclusive" arguments that the experiment ought to proceed. The Board should not be a "blue ribbon panel" of scientists.

4. Paragraph 3 e indicates that ARC accept, in categorical situations, the recommendations of review boards of other agencies in lieu of the ARC review board. This is unsound. The attempt to mortgage responsibility here will in no way exonerate Ames from legal liability in the event of misadventure.

5. Paragraph 4 contains documentation requirements and specifies to be included in consent forms. To the extent that documentation requirements and actual specimen consent forms are contained in the agency-wide proposal, the necessity for much of this paragraph is drawn into question.

6. A cardinal criticism of the Rathert proposal is bound up in the requirement, set forth in Paragraph 1b, for ARC investigators, consonant with the "intent" of the ARC Director, "to ensure that all research conform to the principles and practices expressed in the attached documents A, B, and C". These are Air Force, not NASA, documents. This negates the whole exercise of even formulating, as ARC has done, a proposed agency-wide NMI instruction. NASA must formulate its own principles and practices. Apart from this, Document A contains a formal Air Force abstract entitled "Human Experimentation" and there is annexed to the abstract a bibliography containing a list of NINETY-NINE books, periodicals, and other technical references which advert to human research. It appears to me that if an ARC investigator is obliged to "conform to the principles and practices expressed" in these documents, that unfortunate person would, as a minimum, have to read them. Once again, the instructions for ARC which govern human research should emanate from two completely self-contained documents (a) an agency-wide regulation and (b) the ARC instruction in implementation thereof. The reader should not have to rely upon various documents, external to NASA, for purposes of discerning agency and ARC practice in connection with human research.

HJGlazer:caw 4/21/67

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D R A F T

GENERAL ADMINISTRATIVE PROCEDURE
for the
AMES RESEARCH CENTER
MANNED SYSTEM SIMULATION FACILITIES

1. PURPOSE AND BACKGROUND

   a. This document describes the General Administrative Procedure for test programs to be conducted in the facilities of the Ames Research Center operated by the Simulation Sciences Division. It establishes an Ames Medical Review Board and defines certain responsibilities of the organizational units and persons involved.

   b. By formalizing this procedure, it is the intent of the Director of the Ames Research Center to ensure that all research under his cognizance using human subjects shall conform to the principles and practices expressed in the attached documents A, B, and C. Implicit in this procedure are three mandatory conditions for the use of these facilities:

      (1) Research proposals to use human subjects on the subject facilities must be systematically reviewed, independent of the originator.

      (2) Where the degree of risk is significant, defined hereafter as "Category II or III," it must be assured and documented that all participating human subjects have been appropriately selected, have freely given their informed consent, and have the right to withdraw at any time.

A-2-3a

subject must understand risk - written

specified in 4(b)

(3) When medical research of sufficient risk, defined hereafter as "Category II or III," is being conducted on the subject facilities, there must be at least two physicians involved, one concerned with the welfare of the subject, and one concerned with the sound conduct of the research. These cannot be the same person.

c. The Chief of the Simulation Sciences Division is responsible for operating the equipment under his jurisdiction in accordance with the following procedure, with NMI , and with such temporary or special restrictions as may be imposed by NASA Headquarters or the Director of the Ames Research Center. His decisions in this process are subject to appeal for review by the Office of the Director through the cognizant Assistant Director for Research.

2. PLANNING AND PROGRAM PROCEDURES

a. Figure 1 is an outline of the Planning and Program Procedure. The first formal document is the Proposal, a Memorandum for the Chief, Simulation Sciences Division. This memorandum will present the project protocol in sufficient detail to assess the resources required, to support any unusual priority claims, and to evaluate the medical risk and provisions therefor. Generation of the Proposal document is the responsibility of the originating organization, however, preliminary planning conferences directly with the branches concerned in the Simulation Sciences Division are encouraged for projects of appropriate magnitude,

b. As the second step, the Chief of the Simulation Sciences Division will review the Proposal with appropriate consultation and place the Proposal in one of three categories:

(1) Category I - Negligible risk, either no medical supervision is required at all or the investigator and normal first aid provisions are adequate.

(2) Category II - The degree of risk requires services of a Medical Monitor and documentation of the subject's participation as defined in Section IV. The Medical Monitor must be a licensed physician and may not be the investigator.

(3) Category III - A determination that the degree of risk requires medical review of the Proposal before proceeding further.

This determination will be a subjective judgment based upon the criteria of equipment capability, experience (including the demonstrated capability at the Ames Research Center), physiological end points, and the proposed level of subject information and sophistication. The Simulation Sciences Division Office will maintain up-to-date documents describing the performance specifications of the equipment, failure mode analyses of the equipment, summaries of precedent experience at the Ames Research Center, and summaries of end points and criteria for termination in the literature. It is recognized, however, that by definition cumulative experience never catches up with research and the purpose of Category III is to enforce an independent review of those proposals for which there is no adequate precedent or clear end points and the proper determination is in doubt.

c. The cognizant research Division Chief will next be informed of the category of the Proposal to permit appeal if desired. Category I Proposals will then be regarded as approved when signed by the Chief of the Simulation Sciences Division. Category II Proposals will be referred to the Chief, Medical Services Branch for concurrence and planning and then be regarded as approved. Category III Proposals will be referred to the Ames Medical Review Board for review as described hereafter.

d. Approved Proposals next will be sent to the Chief of the Simulation Experiments Branch or the Simulator Computer Systems Branch as appropriate for completion. In the case of the former, Proposals of appropriate magnitude (including all Category II and III) will require a second document, the Project Development Plan. This document, to be prepared jointly by the Simulation Experiments Branch and the investigator, will stipulate:

(1) experiment protocol, including medical monitoring, instrumentation, and criteria for termination

(2) equipment configuration

(3) personnel, including subject requirements

(4) data reduction requirements

(5) progress report requirements

(6) schedule of events

(7) Experiment Manager (usually SEB personnel, may be investigator by agreement).

e. The Project Development Plan will then be submitted for review and formal approval by the investigator, the Research Branch and Division Chiefs, and as stipulated, the Ames Medical Review Board or the Chief, Simulation Sciences Division.

f. The Experiment Manager will then use the approved Project Development Plan as the basis for coordinating and implementing the technical support of the experiment through appropriate memoranda, work orders, and flight and simulator requests as generally indicated on Figure 1, which is intended to represent current normal operating procedures and responsibilities at the Ames Research Center.

3. MEDICAL REVIEW BOARD

a. There is hereby established an Ames Medical Review Board consisting of the following members:

(1) Chief, Simulation Sciences Division, nonvoting administrative chairman (George A. Rathert, Jr.)

(2) Chief, Medical Office (Dr. Seymour Stein) MD

(3) Chief, Medical Services Branch (Dr. Ralph Pelligra) MD

(4) Dr. John Billingham MD

(5) Dr. Eric Ogden physiologist

(6) Scientist designated by the Assistant Director for Life Sciences

b. The functions of the Ames Medical Review Board are:

(1) To review proposals to use facilities operated by the Simulation Sciences Division which have been judged by the Chief of that

Division to be in Category III as defined above. To decide to reject or approve, with or without stipulations, such Proposals and supporting presentations on behalf of the Director of the Ames Research Center in accordance with established principles and practices of research using human subjects and their own best judgment. In cases of necessity to select and arrange for a jury of medical specialists and refer such Proposals to them for adjucation.

(2) .....) Director's Office may want to specify other
) functions such as reviewing non-SSD research
(3) .....) or annually inspecting the Category I and II decisions.

c. The Ames Medical Review Board is authorized to seek, through the Office of the Director, the services of private consultants or other Government employees to assist in performing the above functions.

d. Proceedings of the Ames Medical Review Board shall be permanently recorded and subject to review by the Office of the Director.

e. Where other U. S. Government agencies are using the subject facilities, the Chief of the Simulation Sciences Division is authorized to accept the evaluation of a duly constituted Medical Review Board of that Agency in lieu of a review by the Ames Medical Review Board.

4. SUBJECTS FOR HUMAN RESEARCH - DOCUMENTATION REQUIREMENTS

a. Placement of research proposals in Category I as defined above implies de facto recognition that the subject is participating voluntarily and may withdraw at any time; however, in view of the negligible risk, no documentation with respect to the subject is required.

b. Human subjects for Proposals in Categories II and III as defined above must be appropriately selected, briefed on the experiment protocol and the likely hazard to the best ability of the investigator, be participating voluntarily, and be able to terminate[1] their participation at any time. Satisfaction of these requirements must be evidenced by a third and final document, the Consent Form, before tests can be conducted.

c. The Consent Form shall include, preceding the witnessed voluntary consent of the subject, brief statements from the Project Development Plan identifying the investigators, the purpose of the research, the subject selection procedure, the monitor instrumentation, and the criteria for termination. The "criteria for termination" shall include the following statements:

(1) All subjects may at any time they desire terminate[1] an experimental run.

(2) The principle investigator, the medical monitor, and the equipment operator (if applicable) also may terminate[1] any experimental run when their judgment indicates.

(3) Any stipulations by the Ames Medical Review Board.

d. To help observe uniform standards and procedures with respect to Section IV, b and c, the Chief of the Medical Services Branch is authorized to maintain records of available subjects, help select and obtain their services, arrange briefing interviews, and supervise the execution of the "Consent Form" as defined herein. The Chief of the Medical Services Branch is required to maintain a permanent file of Consent Forms for all test subjects his Branch is required to monitor.

[1]By "terminate" it is meant that the experiment and apparatus may be brought to a halt in a safe manner with paramount regard for the welfare of the subject.

OPTIONAL FORM NO. 10
MAY 1962 EDITION
GSA FPMR (41 CFR) 101-11.6

UNITED STATES GOVERNMENT

Memorandum

Hearst p.139

EXHIBIT #10

TO : See List Below

DATE: August 23, 1967

FROM : G/Office of General Counsel

SUBJECT: Human Research

Copies of a draft NMI relating to "Human Research" are attached. We would appreciate any comments you may have concerning the draft.

One point: We recognize that paragraph 2 of the draft NMI, which would make the NMI applicable to those contracts and grants in which the NMI is incorporated, immediately gives rise to questions of which contracts and grants should incorporate the NMI and how such incorporation is to be effected. We are working on these matters now. Of course, any suggestions would be appreciated.

Any NMI in the human research area will inevitably present some difficulties. However, we feel that a regulation covering human research is important for the protection of everyone involved -- the subjects of the research, the investigators, and the Government.

Please give the draft your careful consideration.

May we have your comments by October 2, 1967.

Paul G. Dembling
General Counsel

Attachment

Distribution:
D/Office of Organization and Management
F/Office of Public Affairs
Y/Office of University Affairs
RB/Biotechnology & Human Research Division
MM/Space Medicine Division
SB/Bioscience Programs Division
KD/Procurement Office
All Chief Counsels

P140

DRAFT
G/SJG
8-8-67

HUMAN RESEARCH POLICY AND PROCEDURES

1. PURPOSE

This Instruction sets forth certain policies and procedures relating to human research.

2. APPLICABILITY AND SCOPE

This Instruction applies to all human research conducted for or on behalf of NASA by:

a. Any NASA officer or employee;

b. Any NASA contractor, subcontractor (at any tier), or grantee, to the extent that this Instruction is incorporated, by reference or otherwise, in the relevant contract, subcontract or grant.

3. AUTHORITY

Section 203(b)(1) of the National Aeronautics and Space Act of 1958, 42 U.S.C. 2473(b)(1).

4. DEFINITION: "HUMAN RESEARCH"

As used in this Instruction, the term "human research" means any test, experiment, or other evaluation procedure in the course of which, or as a result of which, a human subject may be exposed to conditions which could reasonably be expected to cause distress, pain, impairment of health, physical injury, personality or emotional disorder, or death.

5. RIGHTS OF SUBJECTS

Apart from the obtaining of a proposed subject's consent in accordance with paragraph 8, no subject shall be asked to waive any rights that may arise in connection with any injury, loss or death suffered by the subject as a result of human research.

6. GENERAL PROCEDURAL REQUIREMENTS FOR HUMAN RESEARCH; WAIVERS

a. Except as provided in subparagraph b of this paragraph, all human research within the scope of this Instruction shall be conducted only in accordance with the procedures set forth in paragraphs 7 through 12.

b. In some instances of human research, the requirements set forth in paragraphs 7 through 12 may, for various reasons, not be necessary to protect the subject of such human research. In such instances, upon the request of the principal investigator, the cognizant installation director may, in his discretion, waive some or all of the requirements of paragraphs 7 through 12.

7. EXAMINATION OF SUBJECTS BY PHYSICIANS

a. No human research shall be conducted unless a physician, having been informed of the nature of the proposed human research, finds the subject medically qualified therefor. Such finding shall be based upon an examination of a nature and scope believed by the physician to be reasonable under the circumstances.

b. At the conclusion of the human research, the subject shall be reexamined by a physician.

c. A report of the results of such examination and reexamination shall be promptly forwarded to the cognizant installation director.

8. VOLUNTARY INFORMED CONSENT

a. Except as provided in subparagraph b:

(1) No human research may be conducted unless the subject voluntarily agrees to participate in the human research, has freely given his informed consent in accordance with this subparagraph 8a, and has the legal capacity to so consent.

(2) No consent given by a subject shall be deemed informed unless, prior to the giving of consent, the proposed human research is explained to the subject in language understandable to him. Such explanation must include the nature, duration, and purpose of the human research, the manner in which it will be conducted, and all foreseeable risks, inconveniences, and discomforts to the subject that might result from the conduct of the human research. If the nature of such risks, inconveniences or discomforts is not known, this must be made known to the subject. In addition, the subject must be informed that he may withdraw from the human research at any time, or, if this

is not in fact the case (because the circumstances of the experiment make such withdrawal unwise, dangerous, or impossible), he must be so advised.

(3) Subjects must give their consent in writing in such form as will indicate that the subject has been fully informed of, and voluntarily accepts, the risks, inconveniences and discomforts which may be involved.

b. If the cognizant installation director, based upon information submitted to him by the principal investigator, determines that due to the requirements of the proposed human research (e.g., necessity that the subject be unaware that he is participating in an experiment; nature of experiment requires use of minors), such research would be seriously hampered by any of the requirements of subparagraph a, such director may waive some or all of the requirements of subparagraph a.

9. PROTOCOLS; AUTHORIZATION OF HUMAN RESEARCH BY COGNIZANT INSTALLATION DIRECTOR

a. No human research within the scope of this Instruction may be conducted unless:

(1) The principal investigator has submitted to the cognizant installation director a protocol prepared in accordance with Attachment A.

(2) The cognizant installation director, after considering the protocol of the principal investigator, authorizes the human research.

b. In determining whether the proposed human research should be authorized, the cognizant installation director should consider, among other things, whether:

(1) The importance of the objective of the research outweighs the inherent risks to the subject.

(2) The subject of the human research will be unnecessarily exposed to risk of injury, discomfort or inconvenience.

(3) The subject or his representatives will receive adequate compensation, by reason of insurance, workman's compensation, or the like, in the event the subject suffers any loss, injury or death as a result of the human research.

10. ADVISORY BOARDS

Each installation director may, in his discretion, appoint a board to advise him as to matters within the scope of this Instruction.

11. LEGAL REVIEW

a. A copy of the protocol submitted to the installation director in accordance with paragraph 9, or the waiver request submitted pursuant to paragraph 6, shall be submitted to the appropriate installation counsel's office prior to the conduct of the human research.

b. The cognizant installation director shall consult with the installation counsel's office prior to acting pursuant to paragraph 6, 8b, or 9.

12. REPORTS OF INJURIES AND CHANGES IN PROCEDURES

The principal investigator of human research within the scope of this Instruction shall immediately inform the cognizant installation director in the event of:

a. Any injury to a subject.

b. Any deviation from the procedures set forth in the protocol submitted pursuant to paragraph 10.

13. IMPLEMENTING INSTRUCTIONS BY FIELD INSTALLATIONS

A copy of any installation instruction, notice, policy statement or similar issuance implementing this Instruction shall be forwarded to the appropriate institutional director.

ATTACHMENT A

The protocol to be submitted to an installation director in accordance with paragraph 9 shall provide the following information:

1. The title of the proposed research.

2. Name of NASA organization conducting the research or for which the research is being conducted.

3. Name and qualification of principal investigator (and of co-investigators, if any).

4. Name and qualifications of persons who will conduct the human research (unless covered in item 3).

5. The purpose of the research, including an explanation of why the use of human subjects is required.

6. The plan of study.

7. Historical background of the research, with references to pertinent scientific literature. This should include a discussion of relevant prior research using humans and/or animals.

8. Proposed safety precautions.

9. Expected duration of the study. (Give approximate beginning and ending dates.)

10. Expected number of subjects to be used.

11. The source from which subjects are expected to be obtained.

12. Criteria to be used in selecting subjects.

13. Possible inconveniences, discomforts, pain, and risks to the subject the research may present.

14. Will the subject be free to withdraw from the research at any time? If not, when and why.

15. Wage, salary, or other payment, if any, to be paid to the subject.

16. Source (Federal or state compensation acts, insurance, other) and general description (include examples of dollar amounts) of compensation, if any, to be received by a subject or his representatives in the event of injury. Note: If the human research is to be conducted by NASA employees, this information should be obtained from the appropriate installation counsel's office.

17. Availability of a physician during the research. (Indicate whether a physician will be present at all times; if not, the location of the nearest physician(s) during the performance of the research.)

18. What information concerning the human research is intended to be communicated to the subject. (Include information to be communicated to the subject in the course of obtaining his consent. See paragraph 8 of the Instruction.)

19. The proposed form of consent the subject will be asked to execute.

20. If a determination pursuant to paragraph 6b or 8b has been, or will be, requested, the protocol should so indicate.

APPENDIX #11 p. 148

Penn H file

200-11

J. HENRY GLAZER

Moffett Field, California
January 15, 1968

MEMORANDUM for Assistant Directors, Division Chiefs, Branch Chiefs and Section Heads

SUBJECT: Human Research Experiments Review Board

1. Policies and procedures concerning the planning and approval of all human research conducted for or on behalf of this Center are set forth in AMM 7170-1. Pursuant to paragraph 10 of this issuance, the Human Research Experiments Review Board is hereby established consisting of the following members:

1. Chief, Simulation Sciences Division (George A. Rathert, Jr.) nonvoting administrative Chairman
2. Chief, Medical Office (Dr. Seymour N. Stein)
3. Chief, Medical Services Branch (Dr. Ralph Pelligra)
4. Chief, Biotechnology Division (Dr. John Billingham)
5. Chief, Manned Spacecraft Simulation Branch (Brent Y. Creer)
6. Chief, Environmental Biology Division (Dr. Eric Ogden)

2. The primary function of this Board is to submit recommendations to the Director concerning the suitability and advisability of proposed experiments involving human subjects. Consequently, all protocols required in accordance with paragraph 9 of AMM 7170-1 should be submitted directly to the Board Chairman.

H. Julian Allen
Director

68/6

AMES RESEARCH CENTER

AMM 7170-1

January 15, 1968

MANAGEMENT MANUAL

SECTION: PROGRAM FORMULATION

SUBJECT: Human Research Planning and Approval

1. PURPOSE

This article sets forth general policy and procedures for the planning and approval of research involving human subjects.

2. APPLICABILITY

This article applies to all human research conducted for or on behalf of Ames Research Center by:

a. Any officer or employee of the United States or any other person, entity, or institution.

b. Any NASA contractor, subcontractor (at any tier), or grantee, to the extent that this article is incorporated, by reference or otherwise, in the relevant contract, subcontract, or grant.

3. AUTHORITY

Section 203(b)(1) of the National Aeronuatics and Space Act of 1958 as amended, 42 U.S.C. 2473(b)(1).

4. DEFINITION: "HUMAN RESEARCH"

Notwithstanding other technical usage, the term "Human Research," for purposes of this article, means any test, experiment, or other evaluation procedure in the course of which, or as a result of which, a human subject may be exposed to conditions which could reasonably be expected to cause distress, pain, impairment of health, physical injury, personality or emotional disorder, or death.

5. RIGHTS OF SUBJECTS

Apart from the obtaining of a proposed subject's consent in accordance with paragraph 8, no subject shall be asked to waive any rights that may arise in connection with any injury, loss, or death suffered by the subject

P.150

AMES MANAGEMENT MANUAL

TRANSMITTAL SHEET NO. 89

January 15, 1968

- MATERIAL TRANSMITTED

AMM 7170-1, Human Research Planning and Approval, sets forth general policy and procedures for the planning and approval of research involving human subjects.

- FILING INSTRUCTIONS

Insert the attached in the NASA-Ames Management Manual.

Arthur B. Freeman
Assistant Director for Administration

as a result of human research.

6. GENERAL PROCEDURAL REQUIREMENTS FOR HUMAN RESEARCH: WAIVERS

a. Except as provided in subparagraph 6b, all human research within the scope of this article shall be conducted only in accordance with the procedures set forth in paragraphs 7 through 12.

b. In some instances of human research, the requirements set forth in this article may, for various reasons, not be necessary to protect the subject of such human research. In such instances, upon the request of the principal investigator, the Director may, at his discretion, waive some, or all, of the requirements contained in this article. Moreover, the Director may, at his discretion, categorically waive the requirements of this article, in whole or in part, with respect to classes of trained persons who knowingly follow a specialized calling or occupation which is generally recognized as hazardous including, by way of description but not limitation, the callings of test pilots and astronauts. Nothing contained herein, however, shall be construed as authorizing the use or employment of any person for any purpose if there exists a likelihood that such employment will result in serious or permanent injury or death.

7. EXAMINATION OF SUBJECTS BY PHYSICIANS

a. No human research shall be conducted unless a physician, having been informed of the nature of the proposed human research, finds the subject medically qualified therefor. Such finding shall be based upon an examination of a nature and scope believed by the physician to be reasonable under the circumstances.

b. At the conclusion of the human research, the subject shall be re-examined by a physician.

c. A report of the results of such examination and re-examination shall be promptly forwarded to the Director.

8. VOLUNTARY INFORMED CONSENT

a. Except as provided in subparagraph 8b:

(1) No human research may be conducted unless the subject voluntarily agrees to participate in the human research, has freely

given his informed consent in accordance with this subparagraph 8a and has the legal capacity to so consent.

(2) No consent given by a subject shall be deemed informed unless, prior to the giving of consent, the proposed human research is explained to the subject in language understandable to him. Such explanation must include the nature, duration, and purpose of the human research; the manner in which it will be conducted; and all foreseeable risks, inconveniences, and discomforts to the subject that might result from the conduct of the human research. If the nature of such risks, inconveniences, or discomforts is not known, this fact must be made known to the subject. In addition, the subject must be informed that he may withdraw from the human research at any time, or if this is not in fact the case (because the circumstances of the experiment make such withdrawal unwise, dangerous, or impossible), he must be so advised.

(3) A subject must give his consent in writing in such form as will indicate that he has been fully informed of, and voluntarily accepts, the risks, inconveniences, and discomforts which may be involved.

(4) A person who is a minor or who is without legal capacity to give his voluntary informed consent shall not be a subject of human research without specific authorization in writing signed by the NASA Administrator.

b. The Director may waive some or all of the requirements of subparagraph 8a if he determines that, due to the requirements of the proposed human research (e. g., necessity that the subject be unaware that he is participating in an experiment; nature of experiment requires use of minors when otherwise authorized), such research would be seriously hampered by any of the requirements of subparagraph 8a.

9. PROTOCOLS: AUTHORIZATION OF HUMAN RESEARCH BY THE DIRECTOR

a. No human research within the scope of this article may be conducted unless:

(1) The principal investigator has submitted to the Director a protocol prepared in accordance with Attachment A.

(2) The Director, after considering the protocol of the principal investigator, authorizes the human research.

b. In determining whether the proposed human research should be authorized,

the Director will consider, among other things, whether:

(1) The importance of the objective of the research outweighs the inherent risks to the subject.

(2) The subject of the human research will be unnecessarily exposed to risk of injury, discomfort, or inconvenience.

(3) The subject or his representatives will receive adequate compensation, by reason of insurance, workman's compensation, or the like, in the event the subject suffers any loss, injury, or death as a result of the human research.

10. ADVISORY BOARDS

The Director may, at his discretion, appoint a board to advise him as to matters within the scope of this article.

11. LEGAL AND MEDICAL REVIEW

A copy of the protocol to be submitted to the Director in accordance with paragraph 9, or waiver requests submitted pursuant to paragraphs 6 and 8b, shall be submitted through the Chief Counsel and the Chief, Medical Office.

12. REPORTS OF INJURIES AND CHANGES IN PROCEDURES

The principal investigator of human research within the scope of the article shall immediately inform the Director in the event of:

a. Any injury to a subject.

b. Any deviation from the procedures set forth in the protocol submitted pursuant to paragraph 9.

13. DISTRIBUTION
ADSL-10

H. Julian Allen
Director

January 15, 1968

AMM 7170-1
ATTACHMENT A

The protocol to be submitted to the Director in accordance with paragraph 9 shall provide the following information:

1. The title of the proposed research.

2. Name of organization conducting the research or for which the research is being conducted.

3. Name and qualifications of principal investigator (and of co-investigators, if any).

4. Name and qualifications of persons who will conduct the human research (unless covered in item 3).

5. The purpose of the research, including an explanation of why the use of human subjects is required.

6. The plan of study.

7. Historical background of the research, with references to pertinent scientific literature. This should include a discussion of relevant prior research using humans and/or animals.

8. Proposed safety precautions.

9. Expected duration of the study. (Give approximate beginning and ending dates.)

10. Expected number of subjects to be used.

11. The source from which subjects are expected to be obtained.

12. Criteria to be used in selecting subjects.

13. Possible inconveniences, discomforts, pain, and risks to the subject the research may present.

14. Will the subject be free to withdraw from the research at any time? If not, when and why.

15. Wage, salary, or other payment, if any, to be paid to the subject.

16. Source (Federal or state compensation acts, insurance, other) and general description (include examples of dollar amounts) of compensation, if any, to be received by a subject or his representatives in the event of injury.

17. Availability of a physician during the research. (Indicate whether a physician will be present at all times; if not, the location of the nearest physician(s) during the performance of the research.)

18. What information concerning the human research is intended to be communicated to the subject. (Include information to be communicated to the subject in the course of obtaining his consent. See paragraph 8 of the article.)

19. The proposed form of consent the subject will be asked to execute.

20. If a determination pursuant to paragraph 6b or 8b has been, or will be, requested, the protocol should so indicate.

APPENDIX #12

NASA-Ames

Moffett Field, California
August 5, 1968

MEMORANDUM TO Mr. Ray H. Sutton
Staff Assistant
Grants and Research Contracts

From: Mr. J. Henry Glazer
Chief Counsel

Subject: Proposed grant application from Cardiology Division, Department of Medicine, Stanford University, entitled "Evaluation of the Cardiovascular System During Various Circulatory Stresses"

I have the following questions and observations concerning the above:

1. What is the relationship of the proposed grant to existing contract NAS2-4009 between NASA-Ames and Stanford. The contract is one for "human heart measurements"; the subjects are patients at Stanford; the technical monitor is Dr. Sandler. Is there some duplication here? Ames management is entitled to some explanation as to the distinctions between the proposed grant and the contract. Can the contract be amended in lieu of a grant? If the grant is to be awarded, will the contract be cancelled effective the date of award? There are too many unanswered questions here.

2. The grant instrument must identify the "responsible investigator". He is the person charged with obtaining the voluntary informed consent of subjects, and providing ARC with evidentiary writings in this regard.

3. The grant instrument must specify with particularity Dr. Sandler's role and indicate, among other things,

a. whether he will actually participate in the surgery envisaged

b. and if he does participate, then precisely in what capacity viz: as a "pure researcher" or for the direct benefit of patients or a

combination of these. If for "pure research" or a "combination" of research/direct benefit, this fact will have to be explained to the patient by the responsible investigator and form an element of the patient's consent. Also the origin of the instrument probe will have to be revealed to the patient and he will have to consent to the use of an Ames-made prototype probe.

4. As a result of Dr. Sandler's participation, the grant instrument will have to indicate that any and all functions performed by Dr. Sandler are performed in his capacity as an employee of the federal government. Work he performs pursuant to the terms of reference in the grant may not be considered as "outside employment" since this would amount to conflict of interest even if Dr. Sandler were not compensated by the University.

5. The grant instrument should incorporate by reference AMM 7170-1 and the terms thereof followed.

6. Stanford should furnish Ames with an "Institutional Assurance on Investigations Involving Human Subjects". Ames might use an adaptation of the "Institutional Assurance" required by the Public Health Service. (See page 5 of pamphlet in legal office) Dr. Stein should be consulted as to the substance of the "Institutional Assurance". The Assurance need be executed only once and will cover all grants and contracts between Ames and the Medical School.

7. Pages 14 and 24 suggest that the grant contemplates, in an advanced phase, studies involving "healthy" human beings; hence the realm of "pure research" as opposed to diagnostic, therapeutic or preventive medicine. The prospect of using "healthy subjects" is glossed over in the proposal. It must be fully explained.

8. Page 22: the Form proposed by Stanford is unsatisfactory unless the measures proposed in the grant are exclusively for the direct benefit of a patient and for no other purpose. Now if these measures are exclusively for the direct benefit of patients and for no other purpose the grant instrument must contain the following provision:

> The grantee certifies and specifically acknowledges that each test subject within the meaning and intendment of this grant is a patient admitted for treatment to the Palo Alto-Stanford Hospital Center, and that the grantee shall obtain from each such patient a statement evidencing the voluntary, and informed, consent by such patient to submit to any procedure contemplated within the terms and provisions of this grant; Furthermore, the grantee certifies and acknowledges that notwithstanding the existence of this grant each medical and surgical procedure described herein would, nonetheless, be undertaken and performed on behalf, and for the sole benefit, of each patient who otherwise qualifies, and has been denominated, as a test subject within the meaning and intendment of this grant; And further, that no provision, term, mode of performance, or any other requirement of this grant necessitates deviations from any medical or surgical procedure which would be undertaken, in any event, on behalf, and for the sole benefit, of each of the said patients. Deviations, however slight, if necessitated solely by any provision, term, mode of performance, or requirement of this grant shall not be undertaken or performed unless the test subject involved, after being specifically apprised of the existence of this grant and otherwise fully informed, voluntarily consents to the deviation, and in any such case of deviation a copy of the statement evidencing the voluntary informed consent of the patient involved shall be furnished to the Contracting Officer.

From the language of the grant it appears doubtful that the same is exclusively for the "direct benefit of patients and for no other purpose". Also if this were the case Dr. Sandler's role would be drawn into question since he is not employed by Ames to minister to the needs of hospital patients exclusively for their direct benefit.

9. Page 23 of Proposal: What are "special permission permits"?

10. Regarding Attachment A to AMM 7170-1:

a. Item 13 not adequately answered. Should focus on possible misadventure through

use of Ames-developed "miniature transducer".

b. Items 18 and 19 not adequately answered. Specific, and acceptable, consent forms should be appended to grant instrument along with form for "Institutional Assurance". The grant instrument should designate someone analogous to a "contracting officer" in order to ensure that the various forms are properly executed by grantee.

"Original signed by
J. Henry Glazer"
J. Henry Glazer

cc:
Mr. Allen, 200-1
Mr. Bright, 200-2
Dr. Klein, 200-7
Dr. Stein, 200-9
Dr. Sandler, 239-4A
Mr. Rathert, 243-1

HJG:caw

It is the objective of these studies to analyze the mechanisms for such deteriorations by providing information regarding possible alterations in the, affector, error-sensor and effector arms of the control loop under study. Two control systems will be studied:

(a) baroreceptor system - carotid sinus regulation of arterial blood pressure

(b) vagal system - neural regulation of ionotropic and chronotropic responses of the heart.

Tests will be carried out to determine the static and dynamic responses (by means of pharmacologic agents and/or neuroendocrine mechanisms) of these systems. Studies during acceleration will provide dynamic information at increasing gravitational levels which will hopefully be extrapolatable to zero G conditions.

It is the eventual purpose of these studies to produce a multi-purpose model for the cardiovascular system. It is anticipated that the model will simplify the study of cardiovascular mechanics and identify mechanisms responsible for cardiovascular control as well as to elucidate adaptive mechanisms and uncover those areas in need of further intensive investigation.

3. Human Program:

A major concern for the animal program outlined above is an identification of those major mechanisms whereby animals and man maintain cardiovascular homeostasis in an earth environment. It is the ultimate objective of such studies to create a model from which

predictions may be made concerning maintenance of cardiovascular integrity during longstanding weightlessness, the stresses of reentry and the period immediately following return to earth. Clinical investigation involving human subjects with and without cardiovascular disease will be the only means for obtaining meaningful results. The necessity for studying humans is due to the fact that man has adapted to an erect posture which cannot be easily simulated with presently available experimental animals. Experimental animals will be used when critical measurements cannot be made in man because of lack of appropriate microtransducers or inordinate risk to the human subject.

The initial phase of human studies will involve characterization of primary variables (pressure, volume, flow with respect to time in the cardiac cycle) so as to evaluate the properties of the cardiovascular system. These variables will be monitored by transducers placed on the skin surface or into various vessels (artery, veins) by percutaneous techniques or cut down. The new devices must be compared with current standards of measurement, and the latter require entry into the circulation for blood sampling or injection of materials. Therefore, it has been decided that these initial studies can be done only as part of and at the time of cardiac catheterizations in patients with heart disease. The conduct of such studies will in no way endanger the subject or interfere with collection of data. In all instances the new techniques will complement the catheterization procedure, providing data heretofore not available or improving current methods of data collection. All methods employed will strictly adhere to these.

Approach:

As part of the manned space program of NASA, the Life Sciences Division of the Ames Research Center has developed a number of devices which should have application in the clinical investigations of cardiovsscular functions. Because of the potential value of these instruments to the space program, thorough testing both in animals and man is necessary. The combined program which is outlined will allow these transducers and methods to be evaluated and calibrated.

At the present time there are several devices that would be suitable for study under this proposal. A miniature catheter-tip pressure transducer has been developed which is highly sensitive and is small enough to be introduced into the blood stream through a #17 gauge needle. This device is capable of producing high fidelity intravascular and intracardiac pressure recordings as well as intracardiac heart sounds. Combined with cine-radiographic studies of ventricular function, values for cardiac work, quantitative measurements of valvular insufficiency, correlation of heart sounds with intracardiac dynamics and the effects of intracardiac contrast injections on cardiac function can be studied.

There are a number of specific cardiovascular studies planned in this program. The five studies outlined below represent the initial projects to be undertaken. The staff at Stanford University has developed a great deal of experience with studies of this type as is demonstrated by the publications from the group (see attached

bibliographies). Additional studies will be planned when preliminary evidence for making them meaningful has been accumulated. An outline of the specific studies follows:

(1) Miniature blood pressure transducer.

The blood pressure is one of the cornerstones of cardiovascular response and a technique for its precise measurement is extremely importnnt. In addition, measurement of the pressures generated within the various chambers of the heart is invaluable for an understanding of the function of the heart as a pump.

One such instrument for precise measurement of intravascular and intracardiac pressure is a miniature transducer mounted on the tip of a catheter. This instrument has been developed by Instrumentation Division of NASA. Its small size (1 mm diameter) permits easy entry into the vascular system through an ordinary hypodermic needle or through a cardiac catheter and facilitates manipulation into small blood vessels and the cardiac chambers. This device is extremely sensitive to high frequence pressure oscillations and can, therefore, be used to record intracardiac sounds. Initial efforts will involve calibration and comparison with the standard techniques of pressure measurement.

Methods: Patients undergoing cardiac catheterization and angiocardiography in the Departments of Cardiology and Radiology at Stanford University School of Medicine will be selected as subjects. Pressures will be recorded using the miniature catheter-

tip pressure transducer from various sites in the vascular system and these measurements will be compared with the standard fluid-filled catheter system using Statham P23DB pressure transducers. High speed records will be analyzed both for pressure wave form and amplitude. Using computer techniques Fourier analysis of the pressure wave forms will be performed for purposes of exact comparison.

Patients will be examined at rest, following isoproterenol administration, during and following exercise and during angiocardiography.

Expected results: The instrument to be used has a high frequency response. Accordingly it should yield a more accurate representation of the events occurring within the cardiovascular system than that produced by standard techniques. Some of the confusing aspects of hydraulically recorded pressure traces should be eliminated including those due to catheter entrapment, damping, and resonance within the system.

The recording of intracardiac sounds will be further discussed in another section of this application.

(2) Volume angiocardiographic studies.

Introduction: Angiocardiography is routinely performed in the Radiology Department of Stanford University as part of the evaluation of patients with a wide variety of cardiac and non-cardiac abnormalities.

These studies require injection of radiopaque contrast materials into the heart or blood vessels with simultaneous cine or serial x-ray filming. Using the techniques developed by Sandler and others, an estimation of volume of the various heart chambers can be made using these films. By measuring the rate of change of volume with time over the cardiac cycle it is possible to compute stroke volume, cardiac output, and the work of the heart as it functions as a pump. These parameters are difficult to measure by other means but they are important features of the hydraulic analog of cardiovascular function.

Method: This technique will be validated by conventional estimates of cardiac output (Fick method, dye dilution).

1. Patients with mitral insufficiency will be evaluated before and after surgery for replacement of mitral valve. Left ventricular angiograms will be performed at rest in all instances. In suitable patients, angiocardiograms will also be performed following isoproterenol infusion.

2. Left ventricular angiocardiography will be performed on patients who have idiopathic hypertrophic subaortic stenosis before and after propranolol administration.

3. Left atrial injections will be performed on patients with mitral insufficiency. Particular attention to the change in left atrial dimensions during the various phases of the cardiac cycle will be made in an attempt to validate the concept of systolic expansion of the left atrium as a mechanism for the production of apparent right ventricular heave in patients without pulmonary hypertension.

4. Patients with arteriosclerotic heart disease will be studied using left ventricular injections in an attempt to evaluate the capability of these hearts to perform work.

5. The angiographic studies of volume will be used in association with the high fidelity recordings of intraventricular pressure to determine force velocity curves for intact hearts. This will allow characterization of cardiac function in terms of basic muscle mechanics which have heretofore been available only in isolated preparations.

(3) Fiberoptics instruments - central venous oxygen saturation monitoring:

It has recently been shown that the central venous oxygen saturation may be a useful indicator of cardiac function following acute myocardial infarction. In some cases the first clue to the imminent onset of cardiac failure has appeared to be a drop in the central venous oxygen saturation, which was measured by means of an oximeter.

Thus far, because of the necessity of removing an aliquot of blood from the patient, measurement of central venous oxygen saturation has been intermittent. The use of a fiberoptics instrument would permit constant monitoring of oxygen saturation over long periods of time. Thus, it would be possible to define precisely the value of CVSO2 as a predictor of congestive heart failure and decreased myocardial function.

Methods: Patients will be studied by these means. All will occupy beds in the Palo Alto Stanford Hospital Coronary Care Unit, where it is currently standard practice to insert a central venous catheter for venous pressure measurement. Those patients who, on the basis of extent of infarction, or presence of hypotension or heart block, are most likely to develop congestive heart failure will be studied first. Thereafter, a random selection of good risk patients will be studied.

These investigations will enable us to determine how useful measurement of CVSO2 as an index of myocardial function is in following patients who have sustained myocardial infarction.

(4) Fiberoptics - Aortic insufficiency.

It is known that following the intravenous injection of cardiogreen, there is a discrete increase in arterial dye concentration with each systole. These increments taken together are referred to as a step function, and they can be sensed by a Fiberoptics instrument, with the catheter in the aorta. In aortic insufficiency, the systolic increases in arterial dye concentration occur, but there is also a progressive decrease in dye concentration during diastole. It has been suggested that the degree of aortic insufficiency can be estimated from the change in aortic dye concentration during diastole.

We propose to compare estimates of aortic insufficiency obtained by the fiberoptic method with those derived from left ventricular angiography.

Methods: Ten patients will be studied. Complete right and left heart catheterization will be done, with volume left ventricular angiograms (biplane cine) and estimates of amount of aortic insufficiency by means of dye dilution method. The results of the two methods will then be compared, so that the reliability of the latter can be determined.

(5) Origin of the first heart sound.

The source of the first heart sound has been the subject of controversy. Some ascribe it to closure of the atrioventricular valves per se and some feel that it is not directly due to mitral and tricuspid valve closure.

Recently an adaptation of the aortic valve homograft has been accomplished so as to permit replacement of diseased mitral valves with the homograft. The homograft is sutured to a teflon-covered titanium ring, which is then sewn into the recipient's mitral annulus.

An assessment of the new homograft's function has been done, including left ventriculography. It was noted that when the ring of the homograft is in profile, the movements of the valve leaflets are well seen. Therefore, it will be possible to relate movements of the valve and annulus to heart sounds and ventricular and peripheral arterial pulse contours.

Methods: Eight patients will be studied three to six months following surgery. In addition to hemodynamic evaluations, each will undergo left ventriculography with a simultaneous phonocardiogram and cine-trace. In addition, intracardiac phonocardiograms will be done, while intraventricular pressure is measured by means of the micromanometer (NASA). Several patients will be in normal sinus rhythm at the time of the study.

It will be possible to relate precisely the movements of the mitral valve and annulus to the heart sounds, to give insight into the genesis of the sounds.

E. Appendix

The use of human subjects in this study will be handled in the following manner:

At Stanford University School of Medicine, where the human studies will be carried out, it is necessary to obtain approval for all studies in patients from the Committee on Human Experimentation which has been established to approve all grant proposals for the University. This is a committee made up of members of all of the major clinical departments. The form which is submitted to them for human studies is included with this application. In addition to this, the form necessary for obtaining informed consent from the patient is included.

The human subjects undergoing studies in this protocol will, at the time, have cardiovascular disease and be under investigation for the evaluation of this disease process. The studies carried out in the Cardiac Catheterization Laboratory and the Angiocardiographic Laboratories, where subjects will be having specific pressure and volume measurements with new transducer systems, will be carried out during the course of diagnostic cardiac catheterization and angiocardiography. It is anticipated that the transducer systems used will contribute materially to improving the diagnostic methods on each of these patients and thus may be of primary benefit to the patient in some cases. These patients will be given a full explanation for the procedure, however, and will sign special permission permits for the study to be carried out.

Those patients studied in the Coronary Care Unit and other intensive care unit areas throughout Palo Alto-Stanford Hospital will also have cardiovascular disease. The studies to be carried out in these patients will consist of monitoring their pressures, central venous oxygen saturation and flows under various conditions. These procedures are now standard practice, using other methods of measurement, throughout the hospital. It is our felling that these measurements will aid in the care of these individual patients. The will, however, sign permission forms after being given full explanation for the monitoring techniques to be used. As has been stated, these are standard monitoring techniques for patients in the Coronary Care and Intensive Care Units at the Palo Alto-Stanford Hospital now utilizing different transducer systems.

These assurances for obtaining informed consent and carrying out human studies in patients who have disease where the studies may materially affect the diagnosis and/or treatment of the patient's condition should satisfy the guidelines established by NASA for studies in human subjects. Prior to studying any normal human subjects, additional clarification will be sought from the Committee on Human Experimentation at the NASA installation at Moffett Field. It is not anticipated that this type study will be carried out for the present time.

Evaluation of the Cardiovascular System During Various Circulatory Stresses

SUMMARY

The proposed grant is for the purpose of establishing an exp rimental program for combining the scientific talents of the Cardiology and Radiology Divisions at Stanford University School of Medicine with those of Dr. Harold Sandler in the National Aeronautics and Space Agency program at Moffett Field. Studies will be carried out in human subjects and in aminals to determine the circulatory responses to a number of physiological stresses so that the adaptive mechanisms of the circulatory system in meeting these stresses may be more completely defined. The initial developmental part of the program will involve an evaluation and calibration of new microtransducer systems for recording pressure, flow, volume and the regional distribution of flow. These sophisticated systems will then be used to evaluate the effects of exercise, hypoxia, changes in neuro-endocrine stimulation and pharmacologic alteration on the circulatory system. The analysis of these responses will allow the construction of a mathematical model of the circulator system and the adaptive mechanisms involved in its responses to various types of stresses.

It is anticipated that these studies will provide a background on which predictions can be made regarding the effects of

long-term space flight on circulatory adaptation. Since it is not possible to carry out these studies in human subjects in space flight it is essential that a large body of information be analyzed during circulatory stresses to predict the changes which might occur. The studies outlined in this proposal are primarily directed toward understanding the adaptive circulatory mechanisms which might be important by studying them in experimental animals and in human subjects with disease under a variety of conditions.

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PALO ALTO — STANFORD HOSPITAL CENTER

300 PASTEUR DRIVE — PALO ALTO, CALIFORNIA

CONSENT TO OPERATION, ADMINISTRATION OF ANESTHETICS, AND THE RENDERING OF OTHER MEDICAL SERVICES

Date _____

Hour _____ M. _____

Name of Patient

1. I authorize and direct _____ M.D.

my surgeon and/or associates or assistants of his choice to perform the following operation upon me _____

_____

and/or to do any other therapeutic procedure that (his) (their) judgment may dictate to be advisable for the patient's well-being. The nature of the operation has been explained to me and no warranty or guarantee has been made as to the result or cure.

Exceptions: (if none, so state) _____

_____

2. I hereby authorize and direct the above named surgeon and/or his associates or assistants to provide such additional services for me as he or they may deem reasonable and necessary, including, but not limited to, the administration and maintenance of the anesthesia, and the performance of services involving pathology and radiology, and I hereby consent thereto.

3. I understand that the above named surgeon and his associates or assistants will be occupied solely with performing such operation, and the persons in attendance at such operation for the purpose of administering anesthesia, and the person or persons performing services involving pathology and radiology, are not the agents, servants or employees of the above named hospital nor of any surgeon, but are independent contractors and as such are the agents, servants, or employees of myself.

4. I hereby authorize the hospital pathologist to use his discretion in the disposal of any severed tissue or member, except: _____

Patient's Signature _____

Witness _____

(If patient is a minor or unable to sign, complete the following:)

Patient is a minor _____, or is unable to sign because _____

_____ FATHER

_____ GUARDIAN

_____ MOTHER

_____ OTHER PERSON AND RELATIONSHIP

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STANFORD UNIVERSITY SCHOOL OF MEDICINE

REQUEST for INSTITUTIONAL APPROVAL of CLINICAL RESEARCH and
INVESTIGATION INVOLVING HUMAN BEINGS: ALL SPONSORED RESEARCH

eral Clinical Research Review Committee
nn W. Farquhar, M.D., Chairman

Date_____

pal
igator(s)_____ M.D.
(Name) Ph.D._____
(Title of Position)

No._____ PERIOD: From_____ To_____

of Application: Research Project_____ Research Center_____ Revision_____
Training Program_____ Fellowship_____ Supplement_____
Research Career_____ New_____ Continuation_____
Program Project_____ Renewal_____

APPROVAL OF
TMENT_____ DEPT. EXECUTIVE_____

SIGNATURE PRINCIPAL INVESTIGATOR_____

If this application is a continuation year, and the involvement of human subjects remains
tly as previously approved by the Committee, please initial_____ Principal Investigator.

Describe briefly in the space below the answers to those questions which are pertinent
he referenced project above.

1. Describe exactly the involvement of human study subjects in your research design.
2. State in detail your procedure for obtaining the patient's (minor or adult) informed consent and attach a copy of the consent form which is integral to that procedure.
3. If the administration of personality tests, inventories or questionnaires is integral to your study, indicate how you obtain the subjects informed consent (as in #2), and if you do not, why.

Please send one copy of this form to Doris Hosmer, Rm. E328A (ext. 5271 or 5197). Additio
s are obtainable from Anne Herzberg, Dean's Office (ext. 5524), or Miss Hosmer.

CHANGE IN THE INVOLVEMENT OF HUMAN SUBJECTS IN THE RESEARCH DESIGN REQUIRES AN INVESTIGATOR
OTIFY THE COMMITTEE. A MODIFICATION OF A STUDY, OR AN INTENDED MODIFICATION, IN THIS WAY
TITUTES A NEW RESEARCH PROJECT AND A NEW REVIEW BY THE COMMITTEE ON HUMAN SUBJECTS.

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13

NASA - Ames

Moffett Field, California
8 August 1968

MEMORANDUM to Mr. J. Henry Glazer
Chief Counsel

From: Mr. Ray H. Sutton
Staff Assistant for University Affairs

Subject: Proposed grant application from Cardiology Division, Department of Medicine, Stanford University, entitled "Evaluation of the Cardiovascular System During Various Circulatory Stresses"

1. This note is in response to your memorandum to me, same subject, dated 5 August 1968.

2. I spent the afternoon of Friday 2 August at Stanford conferring with Dr. Harrison, the principal investigator of the proposed grant. The purpose of my visit was twofold. First, I wanted to review the findings of the Human Research Experiments Review Board and to discuss what transpired in the Director's meeting on Friday morning. Secondly, I wanted to work with him in re-writing the proposal in such a manner that it would be acceptable to Ames management.

3. We accomplished a great deal, and a subsequent meeting held in my office on the 7th completed the re-write job. We addressed ourselves to all objections and in particular to those questions and observations raised in your memo.

4. What has resulted is a proposal which, in my opinion, will be completely acceptable to all concerned. It is now being typed and you will be provided a copy for your further review.

5. With respect to NAS2-4009, it is agreed that the contract could be terminated without dire consequences and, as a matter of fact, Dr. Harrison is willing to take the initiative. Before recommending this course of action I would want to gain the views of Dr. Sandler. I'll follow up on this probably next week.

Ray H. Sutton

cc: Mr. Allen, 200-1
Mr. Bright, 200-2
Dr. Klein, 200-7
Dr. Stein, 200-9
Dr. Sandler, 239-4A
Mr. Rathert, 243-1

RHS:kmr

It is the objective of these studies to analyze the mechanism for such deteriorations by providing information regarding possible alterations in the affector, error-sensor and effector arms of the control loop under study. Two control systems will be studied:

(a) baroreceptor system - carotid sinus regulation of arterial blood pressure

(b) vagal system - neural regulation of ionotropic and chronotropic responses of the heart.

Tests will be carried out to determine the static and dynamic response (by means of pharmacologic agents and/or neuroendocrine mechanisms) of these systems. Studies during acceleration will provide dynamic information at increasing gravitational levels which will hopefully be extrapolatable to zero G conditions.

It is the eventual purpose of these studies to produce a multi-purpose model for the cardiovascular system. It is anticipated that the model will simplify the study of cardiovascular mechanics and identify mechanisms responsible for cardiovascular control as well as to elucidate adaptive mechanisms and uncover those areas in need of further intensive investigation.

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A major concern for the animal program outlined above is an identification of those major mechanisms whereby animals and man maintain cardiovascular homeostasis in an earth environment. It is the ultimate objective of such studies to create a model from which

predictions may be made concerning maintenance of cardiovascular integrity during longstanding weightlessness, the stresses of reentry and the period immediately following return to earth. Clinical investigation involving human subjects will be the only means for obtaining meaningful results. The necessity for studying humans is due to the fact that man has adapted to an erect posture which cannot be easily simulated with presently available experimental animals. Experimental animals will be used when critical measurements cannot be made in man because of lack of appropriate microtransducers or inordinate risk to the human subject.

The initial phase of human studies will involve characterization of primary variables (pressure, volume, flow with respect to time in the cardiac cycle) so as to evaluate the properties of the cardiovascular system. These variables will be monitored by transducers placed on the skin surface or into various vessels (artery, veins) by percutaneous techniques or cut down. The new devices must be compared with current standards of measurement, and the latter require entry into the circulation for blood sampling or injection of materials. Therefore, it has been decided that these initial studies can be done only as part of and at the time of cardiac catheterizations in patients with heart disease. The conduct of such studies may prolong the diagnostic study in the patients but is considered to be without substantial risk to the subject or to interfere with the collection of relevant clinical data. In all instances the new techniques will complement the catheterization procedure, providing data heretofore not available or improving current methods of data collection. All methods employed will strictly adhere to these principles.

Approach:

As part of the manned space program of NASA, the Life Sciences Division of the Ames Research Center has developed a number of devices which should have application in the clinical investigations of cardiovsscular functions. Because of the potential value of these instruments to the space program, thorough testing both in animals and man is necessary. The combined program which is outlined will allow these transducers and methods to be evaluated and calibrated.

At the present time there are several devices that would be suitable for study under this proposal. A miniature catheter-tip pressure transducer has been developed which is highly sensitive and is small enough to be introduced into the blood stream through a #17 gauge needle. This device is capable of producing high fidelity intravascular and intracardiac pressure recordings as well as intracardiac heart sounds. Combined with cine-radiographic studies of ventricular function, values for cardiac work, quantitative measurements of valvular insufficiency, correlation of heart sounds with intracardiac dynamics and the effects of intracardiac contrast injections on cardiac function can be studied.

There are a number of specific cardiovascular studies planned in this program. The five studies outlined below represent the initial projects to be undertaken. The staff at Stanford University has developed a great deal of experience with studies of this type as is demonstrated by the publications from the group (see attached

bibliographies). Additional studies will be planned when preliminary evidence for making them meaningful has been accumulated. An outline of the specific studies follows:

(1) Miniature blood pressure transducer.

The blood pressure is one of the cornerstones of cardiovascular response and a technique for its precise measurement is extremely important. In addition, measurement of the pressures generated within the various chambers of the heart is invaluable for an understanding of the function of the heart as a pump.

One such instrument for precise measurement of intravascular and intracardiac pressure is a miniature transducer mounted on the tip of a catheter. This instrument has been developed by Instrumentation Division of NASA. Its small size (1 mm diameter) permits easy entry into the vascular system through an ordinary hypodermic needle or through a cardiac catheter and facilitates manipulation into small blood vessels and the cardiac chambers. This device is extremely sensitive to high frequence pressure oscillations and can, therefore, be used to record intracardiac sounds. Initial efforts will involve calibration and comparison with the standard techniques of pressure measurement.

Methods: Patients undergoing cardiac catheterization and angiocardiography for the diagnosis of heart disease in the Departments of Cardiology and Radiology at Stanford University School of Medicine will be selected as subjects. Pressures will be recorded using the miniature catheter-tip pressure transducer

from various sites in the vascular system and these measurements will be compared with the standard fluid-filled catheter system using Statham P23DB pressure transducers. High speed records will be analyzed both for pressure wave form and amplitude. Using computer techniques, Fourier analysis of the pressure wave forms will be performed for purposes of exact comparison.

Patients will be examined at rest, following isoproterenol administration, during and following exercise and during angiocardiography.

Expected results: The instrument to be used has a high frequency response. Accordingly, it should yield a more accurate representation of the events occurring within the cardiovascular system than that produced by standard techniques. Some of the confusing aspects of hydraulically recorded pressure traces should be eliminated including those due to catheter entrapment, damping, and resonance within the system.

The recording of intracardiac sounds will be further discussed in another section of this application

(2) Volume angiocardiographic studies.

Introduction: Angiocardiography is routinely performed in the Radiology Department of Stanford University as part of the evaluation of patients with a wide variety of cardiac abnormalities.

These studies require injection of radiopaque contrast materials into the heart or blood vessels with simultaneous cine or serial x-ray filming. Using the techniques developed by Sandler and others, an estimation of volume of the various heart chambers can be made using these films. By measuring the rate of change of volume with time over the cardiac cycle it is possible to compute stroke volume, cardiac output, and the work of the heart as it functions as a pump. These parameters are difficult to measure by other means but they are important features of the hydraulic analog of cardiovascular function.

Method: This technique will be validated by conventional estimates of cardiac output (Fick method, dye dilution).

1. Patients with mitral insufficiency will be evaluated before and after surgery for replacement of mitral valve. Left ventricular angiograms will be performed at rest in all instances. In suitable patients, angiocardiograms will also be performed following isoproterenol infusion.

2. Left ventricular angiocardiography will be performed on patients who have idiopathic hypertrophic subaortic stenosis before and after propranolol administration.

3. Left atrial injections will be performed on patients with mitral insufficiency. Particular attention to the change in left atrial dimensions during the various phases of the cardiac cycle will be made in an attempt to validate the concept of systolic expansion of the left atrium as a mechanism for the production of apparent right ventricular heave in patients without pulmonary hypertension.

4. Patients with arteriosclerotic heart disease will be studied using left ventricular injections in an attempt to evaluate the capability of these hearts to perform work.

5. The angiographic studies of volume will be used in association with the high fidelity recordings of intraventricular pressure to determine force velocity curves for intact hearts. This will allow characterization of cardiac function in terms of basic muscle mechanics which have heretofore been available only in isolated preparations.

(3) Fiberoptics instruments - central venous oxygen saturation monitoring:

It has recently been shown that the central venous oxygen saturation may be a useful indicator of cardiac function following acute myocardial infarction. In some cases the first clue to the imminent onset of cardiac failure has appeared to be a drop in the central venous oxygen saturation, which was measured by means of an oximeter.

Thus far, because of the necessity of removing an aliquot of blood from the patient, measurement of central venous oxygen saturation has been intermittent. The use of a fiberoptics instrument would permit constant monitoring of oxygen saturation over long periods of time. Thus, it would be possible to define precisely the value of CVSO2 as a predictor of congestive heart failure and decreased myocardial function.

Methods: Patients will be studied by these means. All will occupy beds in the Palo Alto Stanford Hospital Coronary Care Unit, where it is currently standard practice to insert a central venous catheter for venous pressure measurement. Those patients who, on the basis of extent of infarction, or presence of hypotension or heart block, are most likely to develop congestive heart failure will be studied.

These investigations will enable us to determine how useful measurement of CVSO2 as an index of myocardial function is in following patients who have sustained myocardial infarction.

(4) Fiberoptics - Aortic insufficiency.

It is known that following the intravenous injection of cardiogreen, there is a discrete increase in arterial dye concentration with each systole. These increments taken together are referred to as a step function, and they can be sensed by a Fiberoptics instrument, with the catheter in the aorta. In aortic insufficiency, the systolic increases in arterial dye concentration occur, but there is also a progressive decrease in dye concentration during diastole. It has been suggested that the degree of aortic insufficiency can be estimated from the change in aortic dye concentration during diastole.

We propose to compare estimates of aortic insufficiency obtained by the fiberoptic method with those derived from left ventricular angiography.

Methods: Twenty patients will be studied. Complete right and left heart catheterization will be done, with volume left ventricular angiograms (biplane cine) and estimates of amount of aortic insufficiency by means of dye dilution method. The results of the two methods will then be compared, so that the reliability of the latter can be determined.

(5) Origin of the first heart sound.

The source of the first heart sound has been the subject of controversy. Some ascribe it to closure of the atrioventricular valves per se and some feel that it is not directly due to mitral and tricuspid valve closure.

Recently an adaptation of the aortic valve homograft has been accomplished so as to permit replacement of diseased mitral valves with the homograft. The homograft is sutured to a teflon-covered titanium ring, which is then sewn into the recipient's mitral annulus.

An assessment of the new homograft's function has been done, including left ventriculography. It was noted that when the ring of the homograft is in profile, the movements of the valve leaflets are well seen. Therefore, it will be possible to relate movements of the valve and annulus to heart sounds and ventricular and peripheral arterial pulse contours.

Methods: Twenty patients will be studied three to six months following surgery. In addition to hemodynamic evaluations, each will undergo left ventriculography with a simultaneous phonocardiogram and cine-trace. In addition, intracardiac phonocardiograms will be done, while intraventricular pressure is measured by means of the micromanometer (NASA). Several patients will be in normal sinus rhythm at the time of the study.

It will be possible to relate precisely the movements of the mitral valve and annulus to the heart sounds, to give insight into the genesis of the sounds.

E. Appendix

The use of human subjects in this study will be handled in the following manner:

In order to clarify the human involvement, reference to National Institutes of Health Procedure and Policy Statement #129 as ammended July 1, 1966, and to Ames Research Center Program Formulation #AMM 7170-1 issued on July 15, 1968 is necessary. This proposal was considered by the Stanford University Committee for Insitutional Assurance on Investigations Involving Human Subjects. (The establishment of this committee and its activities are outlined in Attachment A.) The human research is to be conducted in the Cardiology Division, Department of Medicine, and the Diagnostic Division, Department of Radiology, Stanford University School of Medicine, Palo Alto, California, in the Stanford University Hospital.

The principal and responsible investigator is Dr. Donald C. Harrison, Associate Professor of Medicine, Chief of Cardiology Division. The co-investigators for the human research are Dr. Lewis Wexler, Assistant Professor of Radiology, Department of Radiology, and Dr. Ralph E. Gianelly, Instructor in Medicine, Department of Medicine. These individuals are physicians with Board qualification in their subspecialty. All of them have had significant experience in cardiovascular diagnostic methods and in human research. Dr. Harold Sandler will work in association with these investigators and their staff. He will work in this capacity as a government employee and will not be compensated by Stanford. He will not have responsibility for patient management but will perform measurements as part of the clinical investigation. During these studies he will manipulate catheters and do minor surgical procedures. In no case, however, will he have the primary responsibility for the patient since one of the above-named physicians will be in attendance.

Purpose: Three specific purposes are viewed for this human research. First, the testing of new microtransducer systems and their standardization by comparison with older standard transducer systems. Secondly, with the higher frequency resolution for pressures, sounds and rates of change of pressure these new transducer systems will allow more sophisticated definitions of the cardiovascular responses to various circulatory stresses such as exercise, hypoxia and changes in the activity in the sympathetic nervous system. Thirdly, the demonstration that these transducer systems can be used safely for longer periods of time.

Specific plan of study is to use the new micro pressure and sound transducer designed at the NASA installation at Ames for the recording of pressure in the arterial and venous systems and in the various cardiac chambers and for the recording of valvular sounds within the cardiac chamber. These investigations will require its use in approximately 20 patients. Patients who have cardiovascular disease and are undergoing study by standard methods utilizing generally accepted methods for measuring pressure, sound and flow will be used for these studies. None of these patients will be undergoing the study exclusively as a research project. After pressure and sound recordings are made with standard equipment the new and more sophisticated transducer systems will then be used for recording sounds and pressures in the same areas of the heart and vascular system.

In order to study more effectively the function of the heart as a pump and define its activity in mechanical terms it is necessary to do angiographic procedures which allow the study of instantaneous changes in chamber volume. These angiographic studies are carried out in patients for the purposes of diagnosing their cardiac lesions. At the present time with the transducer systems available it is not possible to assess the mechanical function of the heart muscle directly. In approximately 20 patients undergoing angiographic study for diagnostic evaluation of their heart disease special angiographic techniques will be used so that it will be possible to determine the volume and the changes in volume of the cardiac chamber. These do not represent additional studies but represent a change in

the design of the angiographic equipment used for recording the studies. Although the length of an individual study may be prolonged no additional risk of injections of contrast material or catheter manipulation will be involved.

The attempts to assess changes in oxygen saturation by reflectance oximetry utilizing a fiber optics catheter left within the vasculature will be carried out in patients who have had acute heart attacks. At the present time catheters are placed in the vasculature and blood samples withdrawn intermittently for oxygen determinations. In these patients fiberoptics catheters will be introduced and long-term sampling on a continuous basis of oxygen saturation will be possible. Again, this will not be carried out in patients strictly as a research project, but the monitoring which is carried out will be used in patient care and should materially aid these patients. The correlation of these changes in oxygen saturation with the status of the patient will allow a more precise determination of the function of the heart as a pump. In addition to this it should demonstrate the feasibility of long-term monitoring with this type of equipment.

All of the instruments which will be used in these studies have had extensive testing for durability and safety in animals. Their use in humans will allow a more precise evaluation of the function of the heart. They will not, however, be used in normal patients and the information gained with their use should be helpful in determining the necessary treatment for the patient. In view

of the extensive laboratory testing, the hazards from the use such prototype transducer systems should be comparable to that of standard cardiovascular diagnostic procedures. They include the possibility of damage to an artery, the occurrance of a cardiac arrhythmia and the possibility of a blood clot forming on the transducer system being used. All of these hazards are minimal. The instruments will at all times be used under the supervision of the investigators, who are physicians, in a laboratory where standard monitoring techniques on a continuous basis for cardiac arrhythmias has been established. Standard resuscitation equipment and surgical means for correcting any damage to a blood vessel are available in these laboratories. These proposed safety measures are utilized on a continuous basis in the laboratories where these studies will be carried out.

Expected duration of the studies: September 1, 1968, through August 31, 1963. Only a small number of studies will be carried out at any one period of time. It is expected over the period of this grant that at least 80 human subjects will be used for these studies. The subjects will be selected because they are undergoing standard diagnostic procedures for well-established cardiac lesions. These criteria for selection of patients for thes studies have been well-standardized in the Cardiology Division of the Stanford University School of Medicine. They include a patient with significant cardiovascular symptoms in whom cardiac surgery is contemplated. The need for the study is to define more precisely the lesion which exists and how it would be expected to respond to surgery. During the procedure the patient may experience minimal

pain but precautions for local anesthetics and sedation which are given to all patients make it unlikely that significant pain or inconvenience will occur. All patients are free to withdraw from the clinical study and the research at any time. Subjects will not be paid since they are undergoing study for their disease. No means of compensation is provided for patients undergoing such studies. The diagnosis which is determined in these studies will be discussed with the patient. Additional information obtained during investigational procedures will be presented where it helps define the heart disease and function. It is necessary for this to be done for the patient to make a decision regarding whether or not he should have cardiovascular surgery. At the time of discharge from the hospital each patient has a written hospital summary. This hospital summary will be provided to the responsible officials at Ames Research Center. It will specifically state what procedures were carried out in the patient and whether or not any complications ensued. This will be a standard summary which is provided to the patient's referring physician but will include the statement about the use of the transducer system or special angiographic procedure.

Attachment B is a consent form which will be used in these patients. The general nature of the attached human research form of consent is such that it can be used for all of the studies outlined under this proposed grant. No subjects who are minors will be used in this study so no special permission form for consent by parent or guardian is included. The consent form complies with Ames Manual AMM 7170-1, July 15, 1968.

Evaluation of the Cardiovascular System During Various Circulatory Stresses

SUMMARY

The proposed grant is for the purpose of establishing an experimental program for combining the scientific talents of the Cardiology and Radiology Divisions at Stanford University School of Medicine with those of Dr. Harold Sandler in the National Aeronautics and Space Agency program at Moffett Field. Studies will be carried out in human subjects and in aminals to determine the circulatory responses to a number of physiological stresses so that the adaptive mechanisms of the circulatory system in meeting these stresses may be more completely defined. The initial developmental part of the program will involve an evaluation and calibration of new microtransducer systems for recording pressure, flow, volume and the regional distribution of flow. These sophisticated systems will then be used to evaluate the effects of exercise, hypoxia, changes in neuro-endocrine stimulation and pharmacologic alteration on the circulatory system. The analysis of these responses will allow the construction of a mathematical model of the circulator system and the adaptive mechanisms involved in its responses to various types of stresses.

It is anticipated that these studies will provide a background on which predictions can be made regarding the effects of

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long-term space flight on circulatory adaptation. Since it is not possible to carry out these studies in human subjects in space flight it is essential that a large body of information be analyzed during circulatory stresses to predict the changes which might occur. The studies outlined in this proposal are primarily directed toward understanding the adaptive circulatory mechanisms which might be important by studying them in experimental animals and in human subjects with disease under a variety of conditions.

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STANFORD UNIVERSITY
STANFORD, CALIFORNIA 94305

ASSOCIATE PROVOST FOR RESEARCH

Institutional Assurance on Investigations Involving Human Subjects, Including Clinical Research

The Leland Stanford Junior University agrees with the principles of the Public Health Service policy (identified as Policy and Procedure Order 129 dated July 1, 1966) with regard to investigations involving human subjects, including clinical research. This institution agrees that review independent of the investigator is necessary to safeguard the rights and welfare of human subjects of research investigations and assures the Public Health Service that it will establish and maintain advisory groups competent to review plans of investigation involving human subjects, prior to initiation of investigations, to insure adequate safeguard. Group reviews and decisions will be carried out in reference to (1) the rights and welfare of the individuals involved, (2) the appropriateness of the methods used to obtain informed consent, and (3) the risks and potential medical benefits of the investigations.

The institution also agrees to exercise surveillance of PHS-supported projects using human subjects for changes in protocol which may alter the investigational situation with regard to the criteria cited above. The institution further assures the Public Health Service that it will provide advice and consultation to investigators on matters of employing human subjects in investigation, and also that it will provide whatever professional attention or facilities may be required to safeguard the rights and welfare of human subjects involved in investigation. Records of group review and decision on the use of human subjects and of informed consent will be developed and kept by the institution.

Attached as part of this statement are copies of policy and procedure of this institution with regard to use of human subjects in investigation, as well as a description of the groups utilized to review projects for enforcement of these policies and the manner in which the institution will assure itself that the advice of the committee of associates is followed.

Signature: Hubert Heffner

Hubert Heffner

Title: Associate Provost for Research

Date: July 11, 1966

Attachments

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STANFORD UNIVERSITY

Stanford, California 94305

Two University committees exist to assure proper procedures in the conduct of research involving human subjects. The first, concerned primarily with medical research, predates the Public Health Service requirements. It consists of the following members:

Chairman: Dr. John W. Farquhar, Lipid Research
Dr. Malcolm A. Bagshaw, Radiotherapy
Dr. Robert E. Greenberg, Pediatrics
Dr. Donald C. Harrison, Cardiology
Dr. Norman E. Shumway, Surgery

The second committee--a new one--was constituted to deal with research involving questionnaires, psychological tests and experiments, and other procedures involving human subjects in a non-medical content. This Committee is chaired by a Psychologist, and consists of an Electrical Engineer (Associate Provost for Research), a Political Scientist (Associate Dean of the Graduate Division), a Sociologist and an Anthropologist. This Committee has been in place for so short a time that its procedures cannot be meaningfully articulated. However, the letter of appointment sent to Committee members outlines the group's powers. A copy of that letter is attached.

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD. 20014
AREA CODE 301 TELS 496-1000

November 2, 1966

Dr. Hubert Heffner
Associate Provost and Dean of
Research
Stanford University
Stanford, California 94305

RECEIVED
NOV 8 1966
ASSOCIATE PROVOST AND DEAN OF RESEARCH

Dear Dean Heffner:

We are pleased to inform you that the Public Health Service has reviewed and accepted the statement of assurance dated July 11, 1966, and amended October 28, 1966, submitted by the Leland Stanford Junior University, as being in compliance with the requirements contained in PRO #129, revised July 1, 1966, relating to investigations involving human subjects.

Hereafter, applications involving human subjects from the Leland Stanford Junior University for Public Health Service support of research, training, or demonstration projects, including the projects supported through general research support and those of fellows and trainees, are to include the following statement:

> "The investigations encompassed by this application have been or will be approved by the committee of associates of the investigator(s) in accordance with this institution's assurance on clinical research dated July 11, 1966."

It is necessary that the Public Health Service be kept informed on a current basis of any changes in policies, procedures, or committee composition relating to this requirement.

We appreciate your cooperation in this matter, and will welcome suggestions as we continue to study the issues involved in clinical research.

We are much impressed with the careful description of policy and procedure accompanying your statement of assurance. As you might expect, a number of our grantee institutions have requested us to provide a model of acceptable policy and procedure. We would like to help them. Would you have objections to our reproducing your description and our distributing it to institutions that request such a model, or, we believe, would be much assisted by one?

Sincerely yours,

Eugene A. Confrey

Eugene A. Confrey, Ph.D.
Director, Division of Research Grants

STANFORD UNIVERSITY SCHOOL OF MEDICINE

REQUEST for INSTITUTIONAL APPROVAL of CLINICAL RESEARCH and INVESTIGATION INVOLVING HUMAN BEINGS: ALL SPONSORED RESEARCH

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General Clinical Research Review Committee
John W. Farquhar, M.D., Chairman

Date_____

Principal Investigator(s)_____ M.D. Ph.D._____
(Name) (Title of Position)

Title_____

Grant No._____ PERIOD: From_____ To_____

Type of Application: Research Project_____ Research Center_____ Revision_____
Training Program_____ Fellowship_____ Supplement_____
Research Career_____ New_____ Continuation_____
Program Project_____ Renewal_____

APPROVAL OF
DEPARTMENT_____ DEPT. EXECUTIVE_____

SIGNATURE PRINCIPAL INVESTIGATOR_____

If this application is a continuation year, and the involvement of human subjects remains exactly as previously approved by the Committee, please initial_____ Principal Investigator

Describe briefly in the space below the answers to those questions which are pertinent to the referenced project above.

1. Describe exactly the involvement of human study subjects in your research design.
2. State in detail your procedure for obtaining the patient's (minor or adult) informed consent and attach a copy of the consent form which is integral to that procedure.
3. If the administration of personality tests, inventories or questionnaires is integral to your study, indicate how you obtain the subjects informed consent (as in #2), and if you do not, why.

Please send one copy of this form to Doris Hosmer, Rm. E328A (ext. 5271 or 5197). Additional forms are obtainable from Anne Herzberg, Dean's Office (ext. 5524), or Miss Hosmer.

ANY CHANGE IN THE INVOLVEMENT OF HUMAN SUBJECTS IN THE RESEARCH DESIGN REQUIRES AN INVESTIGATOR NOTIFY THE COMMITTEE. A MODIFICATION OF A STUDY, OR AN INTENDED MODIFICATION, IN THIS WAY CONSTITUTES A NEW RESEARCH PROJECT AND A NEW REVIEW BY THE COMMITTEE ON HUMAN SUBJECTS.

(Use reverse side if necessary)

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SPECIAL CONSENT FORM

Part I

1. During the course of your diagnostic evaluation for your heart disease new instruments to measure blood pressure, heart sounds, and heart volumes will be used. The following description of these procedures is included for your evaluation of them. They are investigational but will be checked against the standard types of measuring devices which we use. It is likely that the additional information obtained with these new instruments will be of help to your doctor in deciding whether or not further treatment of your heart condition is necessary.

2. Title: Evaluation of the cardiovascular system during various circulatory stresses.

3. Principal Investigators: Donald C. Harrison, M.D.
Lewis Wexler, M.D.
Ralph E. Gianelly, M.D.

4. Special Investigator: Harold Sandler, M.D. Dr. Sandler will assist the principal investigators in the studies outlined above.

5. Nature of studies. During your catheterization or angiocardiogram, pressures, oxygen saturations and volumes will be recorded by the standard equipment in these laboratories. After this, special measuring devices will be used to record the same values. These measurements are investigational and utilize measuring devices which have been extensively tested in the laboratory. Their use will prolong your study but the risk to you is considered small. The recordings will be made during rest, exercise, and in some cases, drug infusions. We believe these special recordings will give us added information about your heart and allow us to make a better decision about your treatment.

6. Foreseeable inconvenience, risks, and discomfort:

1. Slightly prolong your study.
2. Possible arm pain (local anesthetics will be used)
3. Damage to a blood vessel or blood clots.
4. Cardiac arrhythmias

Every effort to assure no complications will be made.

Donald C. Harrison, M.D.
Chief, Cardiology Division

DCH:bc

Part II - To be completed by patient

NOTE TO THE PATIENT: READ PART I CAREFULLY. IF THERE IS ANYTHING IN PART I YOU DO NOT UNDERSTAND, ASK ONE OF THE DOCTORS WHO WILL BE CONDUCTING THE STUDY FOR AN EXPLANATION.

(a) I hereby agree to participate, as a patient, in the tests described in Part I of this form.

(b) I am aware of the possible foreseeable harmful consequences that may occur. The doctors have explained the procedures to me in a language which I can understand.

(c) I acknowledge that my consent has been freely given and that I may withdraw my consent at any time.

The foregoing shall not be construed as a release of the physicians of Stanford Medical School from any future liability arising from or in connection with the tests or experiments in which I am to participate as a subject.

Signature of subject

Date

Appendix #14
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NASA-AMES

Moffett Field, California
February 26, 1968

MEMORANDUM to J. Henry Glazer, Esq.
Chief Counsel

From: Joel S. Primes
Law Clerk

Subject: Protections afforded under the laws of California to contractor employees who are the subjects of human research within the meaning of Paragraph 2b of AMM 7170-1

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INTRODUCTION

California's compensation statute is a liberal law, construed to afford maximum protection to persons within the direct scope of industrial physical risks and financial losses. It is composed of an exclusive system of employer liability without fault, based upon insurance concepts. Rights and remedies of the system's beneficiaries rest upon status in an employer-employee relationship rather than upon either tort or contract principles. The purpose of the law is rehabilitation, not indemnification for damages under negligence law. CEB: California Workmen's Compensation Practice, § 1.28 (1963).

The imposition of liability without fault and the statutory admonition of "liberal construction" in favor of compensation coverage reject common law concepts of tort liability. Moreover, Cal. Const. Art. XX, § 21 authorizes the administrative procedure for handling workmen's compensation, providing that "the administration of such legislation shall accomplish substantial justice in all cases expeditiously, inexpensively, and without incumbrance of any character".

The Roseberry Act, Stats. 1911, ch. 399, eliminated the fellow servant and assumption of risk doctrines and markedly proscribed the contributory negligence rule. Lab. C. 2801 states:

"It shall not be a defense that:

a) The employee either expressly or impliedly assumed the risk of the hazard complained of."

The risk of the "hazard complained of" has been interpreted to include both the ordinary and extraordinary risks of the employment. Tubbs v. Stone & Webster Constr. Co., 159 P. 242, 30 C.A. 705 (1916). In Tubbs, employees after emptying their wheelbarrows, ordinarily continued around an elevated circular runway to a refilling point. The plaintiff was injuried when he fell off the runway while passing another employee when he returned the same way he came pursuant to an order from his foreman. The court, 159 P. at 245:

"The act does not use the expression "risk of the employment" but

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"risk of the hazard complained of", and this is broad enough to include both the ordinary and extraordinary risks of an employment".

The assumption of the risk defense being statutorily eliminated combined with the liberal interpretations given Workmen's Compensation laws by California courts leads to the conclusion that recovery under the Act would not be barred by an employee who voluntarily assumes the risk of participating in a hazardous experiment as a part of his employment. The Tubbs case displays the liberal approach used by the courts to allow recovery. The California Workmen's Compensation legislation was painted with a broad brush to allow judicial discretion with a view toward protecting employee's injured on the job.

EMPLOYEES COVERED BY WORKMEN'S COMPENSATION LAW

There is a presumption that any person rendering service for another, other than as an independent contractor, or unless expressly excluded, is an employee. Lab. C. § 3357. Additionally, however, either to clarify the law or for reasons of public policy, the Legislature has defined "employee" as every person in the service of an employer under any appointment or contract of hire or apprenticeship, express or implied, oral or written (Lab. C. § 3351). The following classes of workers have been singled out as groups for special inclusion:

1) Persons unlawfully employed (Lab. C. § 3351).
2) Aliens (Lab. C. § 3351a).
3) Minors, Ibid.
4) Elected and appointed paid public officers (Lab. C. § 3351b).

If the injured person was actually performing service for the alleged employer at the time of the injury, the burden of proof to exclude him from the protection of the act, as an independent contractor or otherwise, is on the alleged employer. Lab. C. § 5705. However, if the service is voluntary and without compensation, there may be no employment relationship on which the employee can sue under the act. Edwards v. Hollywood Canteen, 27 C.2d 802, 167 P.2d 729 (1946).

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JURISDICTION

If the employment contract is entered into in California, the Workmen's Compensation Appeals Board has jurisdiction over the employee's injures even where they occur on the property under the exclusive jurisdiction of the United States. 40 U.S.C. §290, effective June 25, 1936. See appendix for complete text of § 290.

40 U.S.C. § 290 provides that State compensation authorities may apply the local compensation laws to federal property within their respective boundaries in the same manner as though such property were under the exclusive jurisdiction of the State. The statute revests State jurisdiction which, presumably Congress thought might be divested by the acquisition and ownership of the land by the United States for Federal purposes. Thus for purposes of workmen's compensation laws the United States of America has vested in the several States within whose exterior boundaries such place may be the right, power, and authority to apply the applicable States workmen's compensation laws.

The case of Travelers Ins. Co. v. Cardillo, 141 F.2d 362 (1944) displays the functions to be performed by the statute:

> "The effect of the federal statute extending state workmen's compensation laws to buildings of the United States was to restore the status quo ante, and the purpose was to make sure that contractor's employees working on federal buildings in a federal area would be able to recover compensation benefits for disability or death".

The remedy under § 290 is exclusive. In Waliach v. Lieberman, 219 F. Supp. 247 (1963) an injured painter was precluded from any recovery where he had recovered in the State compensation proceedings. The painter was injured when working in a post office building and it was held that the applicable State's workmen's compensation laws were binding.

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EXCLUSIVE REMEDY UNDER COMPENSATION LAWS

The California compensation act provides that the liability for compensation it furnishes is "in lieu of any other liability whatsoever[1] to any person.....without regard to negligence", that may "exist against an employer" for any injury or death arising out of and in the course of the employment. Lab. C. § 3600. Therefore, when the conditions of compensation concur (Lab. C. 3600) and the employer has insured the payment of compensation benefits by the required insurance carrier (Lab. C. 3700), the right to recover compensation under the Labor Code is the exclusive remedy for injury or death of an employee against the employer. Lab. C. § 3601, § 5301; Law v. Dartt, 109 C.A. 2d 508, 240 P.2d 1013 (1952).

In addition to this limitation phrased in terms of the employer's liability the statute declares that except where the employer has failed to insure the payment of compensation, the right to recover compensation is the "exclusive remedy" against the employer for injury or death wherever the conditions of compensation exist. Lab. C. § 3601. Popejoy v. Hannon, 37 Cal.2d 159, 231 P.2d 484 (1952).

The exclusive compensation law remedy supersedes the common law in the field of injury to workmen in the course of their employment and creates a different standard of rights and obligations in substitution of all prior rights and actions against such an employer based on the fact of the employee's injury or death. Treat v. Los Angeles Gas & Elec. Corp., 82 Cal. App. 610, 256 P. 447 (1927). Where the employee's injury is within the scope of the compensation laws, and the employer is in fact insured, a court of law has no authority to render judgment for recovery of damages by the employee from the employer. Baugh v. Rogers, 9 C.C.C. 141, 144 Cal. 2d 200. Late?

1. Except where the employer has failed to secure the payment of compensation in which event Lab. C. § 3706 becomes applicable.

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EMPLOYER'S FAILURE TO INSURE

A) Unintentional Failure: -

If an employer fails to obtain insurance or to self-insure as required by the compensation act, an injured employee, or his dependents in the event of the employee's death, are entitled to maintain an action at law for damages, or to file an application for compensation with the Industrial Accident Commission, or both. Lab. C. § 3706. The action for damages may be brought against the uninsured employer even though he has voluntarily met the requirements of compensation by furnishing all necessary medical care and payment of wages during the period of disability. Ciffin v. Bloodworth, 28 C.A.2d 522, 82 P.2d 953 (1938).

The employer is deprived of the defenses of contributory negligence, assumption of risk, and fellow servant rule. It is presumed that the injury was due to the employer's negligence. Lab. C. § 3708; Goss v. Fanoe, 114 C.A.2d 819, 251 P.2d 337 (1952). This presumption of negligence of the uninsured employer may be rebutted by evidence to the contrary. Judd v. Chabek, 162 C.A. 2d 574, 328 P.2d 245.

The employee may even attach the property of the employer in an amount fixed by the court (Lab. C. § 3707) or the Commission may direct the issuance of an attachment to secure a possible compensation award (Lab. C. § 5600). If a final award against the uninsured employer remains unpaid for more than ten days, the Labor Commissioner may take an assignment of it for enforcement. Lab. C. § 4555.

B) Willful Failure:

If the failure to insure is willful, the employer may be liable for additional penalties. He may be criminally prosecuted and his business may be abated as a public nuisance if the violation is continued. Lab. C. § 3712. In addition, there must be a ten per cent increase in the amount of compensation awarded to the injured employee, and the employer may be liable for all attorney's fees. Lab. C. § § 4554, 4555.

The only remedy of an employee injured while working for an excluded employer is a civil suit for damages. The basis of the suit must be negligence on the part of the employer. Lab. C. § 2801. Those employers not subject to state jurisdiction may, by affirmative action, bring themselves within the application of the compensation law, and their failure to do so, if the matter has been given deliberate consideration represents an exercise of a personal choice. Lab. C. § § 4150-4156.

EMPLOYER'S DUTY OF CARE:

The employer is required to indemnify his employee for losses caused by the employer's want of ordinary care. Lab. C. § 2800. The employer must furnish safe employment and a safe place of employment, using all safety devices and all practices, methods, and operations which are reasonably adequate to render such employment and place of employment safe. Lab. C. § § 6400-6403. The construction, occupancy, or maintenance of an unsafe place of employment is forbidden by law Lab. C. § § 6404, 6405. The employer is not, however, required to furnish a place of employment or appliances which are absolutely safe, but only those which are reasonably safe, having regard to the character of the work. Tellez v. Schreyer, 158 Cal. App. 2d 248, 322 P. 2d 259 (1958).

The employer is under a duty to make reasonably careful inspections at reasonable intervals to learn of dangers that are not apparent. The extent and frequency of such inspections depend on the nature of the things to be inspected, the danger to be anticipated if inspections are not made, and other factors which show the reasonableness of the employer's conduct. Devens v. Goldberg, 33 Cal. 2d 173, 13 C.C.C. 293.

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EMPLOYMENT CAUSING EMPLOYEE TO OCCUPY DANGEROUS POSITION

When a person's employment brings him into a position that becomes, or is dangerous, and he is injured there while acting in the scope of employment, California courts have often allowed recovery. The following cases exemplify the extreme positions taken by various California courts to uphold benefits to employees injured while on the job. They show that the defense of assumption of risk has no basis in determining recovery against the employer for injuries to employee's occurring within the scope of the employee's employment.

In Industrial Indem. Co. v. Industrial Acc. Com., 95 C.A.2d 804, 214 P.2d 41, an employee of an inn acting as a bartender was killed by a shot intended for a customer during an altercation in which the employee took no part, his death was held to have arisen out of the employment.and was therefore compensable. The court reasoned that since the employment required him to be in what turned out to be a place of danger, then the injury occurred in a hazardous occupation or location. Recovery was also allowed in Frigidaire Corp. v. Industrial Acc. Com., 103 C.A.27, 283 P. 974 where an employee was required by his employment to travel between various cities by public transportation, and he was struck and killed, while standing on the edge of a railroad station platform adjacent to the street, by a stray bullet fired by a policeman at a suspected criminal.

In considering whether an injury arose "out of" and was "proximately caused" by the employment, questions of workmen's compensation are not controlled by common-law rules of proximate cause applied in tort cases, and reasonable doubts whether an injury is compensable should be resolved in favor of the employee. Truck Ins. Exch. v. Industrial Acc. Com., 27 C.2d 813, 167 P.2d 705; 55 Cal. Jur. 2d 69. An employee was even entitled to compensation where he was injured by reason of the collapse of a floor above his work room, though the collapse was not due to a structrual defect, but rather to an unauthorized use a tenant made of the room above. Kimbel v. Industrial Acc. Com.,, 173 C. 351, 160 P. 150,

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Lab. C. § 3600 provides as a condition of compensation that an injury to an employee must arise out of his employment. This requirement refers to a causal connection between the employment and the injury. Scott v. Pacific Coast Borax Co., 140 Cal.App.2d 173, 294 P.2d 1039 (1956). Madin v. Industrial Acc. Com., 46 Cal.2d 90, 292 P.2d 892 (1956) is dispositive of the liberal interpretation invoked by an analysis of causal connection for a conclusion that an injury arose out of employment. In Madin, the employees were a husband and wife who were on 24-hour duty as caretakers and managers of rental property owned by their employer. They were injured when a bulldozer, which was being used on property in the neighborhood, was started by some boys and pushed through the walls of their bedroom. Neither the bulldozer nor the boys were under control of the employer. In finding that the injury arose out of the employment, the court held that a sufficient causal connection between the injury and the employment is shown where the employment was a contributory cause of the injury, that where the injury occurs on the employer's premises while the employee is in the course of his employment the injury also arises out of the employment unless the connection is so remote from the employment that it is not an incident thereof, and that an injury can arise out of the employment even though the employer had no connection with or control over the force which caused the injury.

Madin also held that an injury is compensable where the employee is brought into a position of danger by the employment even though the risk could not have been forseen by the employer. The case also stated that all reasonable doubts as to whether an injury is compensable are to be resolved in favor of the employee.

In Wiseman v. Industrial Acc. Comm., 46 Cal.2d 570, 297 P.2d 649 the principles of Madin were held to permit compensation to the family of an employee who was burned to death as a result of careless smoking in a hotel room while in the course of his employment. The decision is another reflection where the court felt that the employee's injuries were sufficiently connected with the employment to be said to arise therefrom.

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EMPLOYER'S LIABILITY FOR INTENTIONAL TORTS:

An employee intentionally assaulted by his employer has a choice of forums inwhich to seek recovery, and possibly a choice of remedies. Carter v. Superior Ct., 142 Cal.App.2d 350, 21 C.C.C. 234. It is well settled that an employee may assert that the injury occurred by reason of a risk or condition incident to the employment, notwithstanding the fact that it was intentional, and seek compensation before the Workmen's Compensation Appeals Board; or he may treat his injury as not having arisen out of and in the course of employment and seek damages in an action at law. Azevedo v. I.A.C., 243 Cal. App.2d 379 (1966). But of course an employee may not recover both compensation benefits and damages. Carter v. Superior Ct., supra.

The leading, and quite unique, case upholding civil liability of an employer who was also liable for compensation benefits is Duprey v. Shane, 39 Cal.2d 781, 249 P.2d 8 (1952). In Duprey the employer, a chiropractor, treated the employee for the industrial injury and was held to be subject to a malpractice action for aggravation of the injury just as he would have been if he had not been the employer.

SERIOUS AND WILFUL MISCONDUCT:

a) Serious and Wilful Misconduct of Employer.

If an employee is injured through serious and wilful misconduct of the employer or certain designated employer representatives, he is entitled to an increase of one half in the amount otherwise recoverable, to the maximum increase of $ 7500.00, plus costs and expenses not to exceed $ 250.00. Lab. C. § 4553. This action is directed against the employer, not the insurance carrier, since the latter cannot insure against such liability. Ins. C. § 11661.

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In Keeley v. I.A.C., 55 C.2d 261, 359 P.2d 34 an injured employee presented a good claim of serious and wilful misconduct against his employer when he established that the employer's representative ordered him into a known place of danger, knowing that injury would result if a motor was started, without taking some precautions to protect against the known danger. In Gordon v. Industrial Acc Com. 199 Cal. 420, 249 P. 849 an employee was killed in a cave-in of a gravel pit. It was held that compelling an employee to work in a dangerous spot, without taking protective measures, and where the employer knows or should know of the danger constitued serious and wilful misconduct.

The leading California case on the meaning of serious and wilful misconduct, Mercer-Fraser v. I.A.C., 40 Cal.2d 102, 251 P.2d 955 (1953) made it clear that negligence of any degree, including gross negligence, does not constitute serious and wilful misconduct. The rationale being that negligent misconduct does not involve an intention to perform an act that the actor knows will probably cause harm. In determining the meaning "serious and wilful misconduct" of the Lab. C. § 4553, the court quoted judicial interpretations of "wilful misconduct" under the automobile guest statute (Veh. C. § 17158), and concluded that "serious and wilful misoonduct" cannot be established by showing acts any less culpable, any less deliberate, or any less knowing or intentional, than is required to prove "wilful misconduct".

b) Serious and Wilful Misconduct of Employee:

Where an employee's injury is caused by his own serious and wilful misconduct, the compensation otherwise recoverable is reduced by one-half. Lab. C. § 4551. Exceptions are made where the injury results in death (Lab. C. § 4551a); permanent disability of 70 o/o or over (Lab. C. § 4551b); from the employer's failure to comply with any safety law or order (Lab. C. § 4551c) or, where the injured employee is under sixteen years of age at the time of the injury (Lab. C. § 4551d).

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Where none of the above exceptions favor the employee, and both the employee and the employer are guilty of serious and wilful misconduct, normal compensation is awarded. Walker v. Artic Ice Mach. Co., 19 I.A.C. 48. The standard used for serious and wilful misconduct is the same for employer and employee.

If a workman is unaware of the danger involved in his act, the element of wilfulness to risk that danger is missing and therefore his conduct cannot be serious and wilful. Brooklyn Mining Co. v. I.A.C., 172 Cal. 774, 159 P. 162 (1916). The ruling would be otherwise if the danger is obvious to any person with the workmen's experience, and the workmen deliberately enhances that danger by removal of a safety device. Bayshore Laundry Co. v. I.A.C., 26 Cal. App. 547, 172 P. 1128 (1918).

ASSUMPTION OF RISK: ANALYSIS OF CALIFORNIA CASE LAW

The defense of assumption of risk in California is quite narrowly confined and restricted by two requirements: first, that the plaintiff must know and understand the risk he is incurring, and second, that his choice to incur it must be entirely free and voluntary. This rationale was aptly explained by Prosser, in his book on Torts (2d ed. 1955) page 309:

> "Knowledge of the risk is the watchword of assumption of risk. Ordinarily the plaintiff will not be taken to assume any risk of conditions or activities of which he is ignorant. Furthermore, he must not only know of the facts which create the danger, but he must comprehend and appreciate the danger itself.....If because of age, or lack of information or experience, he does not comprehend the risk involved in a known situation, he will not be taken to consent to assume it". (Emphasis supplied)

The above analysis by California's leading tort expert would lead to an inference that if the employee was "not fully apprised of the risk", or if the injury involved was "beyond the risk explained to him", the employee could not legally be held to have assumed a risk he did not comprehend or appreciate.

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Prosser's definition of assumption of risk has frequently been stated and applied by California courts. In Saeter v. Harley Davidson Motor Co., 186 Cal. App.2d 248, it is pointed out that before the doctrine is applicable the victim must have "appreciation of the danger", and that such requirement is independent of the requirement of actual general knowledge of a danger. In other words, actual knowledge of a danger is not interchangeable with appreciation of the risk. In Vierra v. Fifth Ave Rental Service, 32 Cal. Rptr. 193, 383 P.2d 777 (1963) the court held that the fact that the plaintiff is fully aware of one risk, does not mean that he assumes another of which he is unaware. Thus where plaintiff building occupant knew only of danger from flying particles of concrete within a range of seven feet from the work of cutting a door through concrete in a wall, he did not assume any risk of injury at a distance of at least nine feet from a flying fragment of steel from a tool being used. The court 32 Cal. Rptr at 196 further stated:

> "To warrant the application of the doctrine the evidence must show that the victim appreciated the specific danger involved. He does not assume any risk he does not know or appreciate. Stated another way, before the doctrine is applicable, the victim must have not only general knowledge of a danger, but must have knowledge of the particular danger, that is, knowledge of the magnitude of the risk involved." (Emphasis supplied)

Actual knowledge of the existence of a specific danger is an essential and indispensable element of the defense of assumption of the risk. It is not enough that the plaintiff should have been aware of that danger. There must be evidence sufficient to show that he was actually aware of it. This element of the doctrine has been found missing in a number of different factual situations by California courts. In Bee v. Tungstar Corp., 65 Cal. App.2d 729, 151 P.2d 537 it was held that an invitee who knew of the general danger in riding in a bucket of the mine owner's aerial tramway, did not assume the risk, of which he had no specific knowledge, that the traction cable was improperly spliced.

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In Hidden v. Malinoff, 174 Cal. App.2d 845, 345 P.2d 499, the decedent stepped out of his car onto the traveled portion of a main highway in the nighttime. Traffic was heavy and he was warned by his wife not to open the hood of the car which opened from the side towards the traffic. Plaintiff alighted from the car, turned his back to oncoming traffic and was hit by defendant's negligently operated car. Obviously plaintiff must have known that it was dangerous to do what he did, and the appellate court so held. But it also held that it was prejudicial error to instruct on assumption of risk because there was no evidence that plaintiff knew of the actual risk involved, namely the negligent operation of the defendant's car.

Hall v. Macco Corp., 198 Cal.App.2d 415 is a case involving two separate dangers, one known and one unknown. In that case the denial of assumption of risk instructions was upheld where the plaintiff was watching a burning bridge when a gas line under the bridge, of which the plaintiff had no knowledge, exploded. Plaintiff knew of the general danger of approaching the burning bridge but not of the specific danger of the gas line. In Hook v. Point Montara Fire, etc., 213 A.C.A. 111, 28 Cal. Rptr. 560, it was held error to instruct on the doctrine where the plaintiff may have known of the general danger of walking into a darkened room, but did not know that the floor level was nine inches lower than the thresold of the door. The court reasoned:

"....before one can consent to assume a risk he must have knowledge of the particular risk to which he is consenting....."

As stated in Dutcher v. City of Santa Rosa High School District, 137 Cal. App.2d 481, 290 P.2d 318: "before the defense of assumed risk can succeed the evidence must disclose either actual or implied knowledge of the risk and an appreciation of the magnitude thereof". In Dutcher an action was brought against a high school district and an automobile mechanics teacher for death of the first student and injuries to a second student as a result of an explosion which occurred at the high school. The explosion occurred when a third student attempted to burn a hole in an automobile, which had an open gasoline tank with an acetylene torch. The court in considering the defense of assumption of risk reasoned:

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"To be sure, they knew that the student was operating a torch, but there is no showing that they knew either how close the tank that exploded was to the flames and sparks being emitted by the torch or that they appreciated the danger of explosion if flames or sparks from the torch ignited gases issuing from the tank".

It is now clearly seen that in addition to knowledge of the condition creating the risk, an appreciation of the magnitude of that risk is a vital element in the defense of assumption of risk. Knowledge of the exact risk is essential if an adequate comprehension and appreciation of that risk is to be found. Therefore an employee injured in the ARC centrifuge cannot be said to have assumed a risk he is "not fully apprised of" or of an "injury beyond the risk explained to him". If the risk is beyond that explained to him or he is not fully apprised of it, how could he possibly comprehend and appreciate the danger?

FEDERAL TORT CLAIMS ACT:

The Federal Tort Claims Act permits recovery on claims for money damages "for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred". 28 U.S.C. § 1346(b). Claims arising out of assault, battery and other specified intentional acts are excluded from coverage under the Act. 28 U.S.C. § 2680.

Thus while federal law and the Rules of Civil Procedure control the procedural aspects of the suit under the Tort Claims Act, it is state law that determines whether the ultimate facts give rise to a cause of action in favor of the claimant. Richards v. United States, 369 U.S. 1, (1962). State characterization of wrongful conduct as being either a battery or as negligence is therefore determinative of recovery under the Federal Tort Claims Act.

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The following analysis of California tort definitions may shed light upon possible characterization by that State of conduct deemed actionable as an intentional tort or as negligence. Prosser defines "battery" as the "unpermitted, unprivileged contacts with his person, caused by acts intended to result in such contacts, or the apprehension of them, directed at the other or a third person". Prosser on Torts (2d ed. 1955) § 9, p. 30. The essence of the tort of battery is the intentional act by the defendant. He must intend a result to follow, or must believe that the result is substantially certain to follow from his act. Prosser, supra, § 8, p. 29. The act must cause, and must be intended to cause, an unpermitted contact. Mere negligence, or even recklessness, which creates only a risk that the contact will result, may afford a distinct cause of action in itself, but under modern usage of the term it is not enough for battery.

It seems reasonable to assume that those in charge of the ARC centrifuge would not intend to injure, or place employee's where they believed there was a substantial certainty that an injury would occur. If this assumption is valid, an injury "beyond the risk explained" or "not fully apprised of by the employee" should not be characterized by California courts as a battery. The essential element of intent would be lacking. It seems most probable that the terms "wrongful act" would be expanded to encompass this tortious conduct which caused the injury.

Could operation of the ARC centrifuge fall within classifaction of an ultrahazardous activity? Prosser, supra, p. 532 (3d ed.) states that he feels "experimental aircraft and military planes not designed primarily for safety" should come under this category. However, Harris v. United States, 205 F.2d 765 held that under the Federal Torts Claim Act some misfeasance or nonfeasance is necessary because the Act does not impose liability without fault. This does not mean that inherently dangerous activities have not been successfully argued to establish governmental liability under the Federal Torts Claim Act. Lester S.

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Jayson: Handling Federal Tort Claims, § 214.01, fn. 2, p. 9-19 lists a number of cases where liability for injury from an inherently dangerous object was denied or found to exist depending upon the proof of negligence established by the plaintiff. Therefore the ultrahazardous nature of the ARC centrifuge might be successfully used to establish negligence against the Government where an injury is proximately caused by operation of the ARC centrifuge.

If the claimant sustains damage through the conduct of government employees which is regarded as tortious and actionable under state law, but which does not constitute negligence or one of the expressly excluded claims, it very likely will be held "wrongful" and therefore actionable under the Tort Claims Act. Jayson, supra, § 214.04. In light of the inherently dangerous activity involved in the use of the ARC centrifuge, combined with the use of res ipsa loquitur a cause of action framed in negligence might be sustained from almost any injury proximately caused by the use of the ARC centrifuge.

FEDERAL EMPLOYER'S LIABILITY ACT

As a last resort the injured party may argue that he was performing beneficial services for the Federal Government in a capacity which infers that he should be classified as a government employee. Because only Congress can authorize federal employees, the Court of Claims in Washington D.C. would resolve the issue. In the past the court has been very liberal in finding the claimant to be an employee so that recovery under the Act may be sustained.

The Supreme Court in Tiller v. Atlantic Coast Line R.R. Co., 318 U.S. 54, 63 Sup. Ct. 444, held that "every vestige of the doctrine of assumption of risk has been abolished" under the Federal Employer's Liability Act. This is also the case under the Federal Employees' Compensation Act, 5 U.S.C. § 8144.

BENEFITS UNDER CALIFORNIA WORKMEN'S COMPENSATION

a) Death Benefits:

The enclosed schedules should list the various benefits provided by the Act. When employee sustains industrial injury that proximately causes his death, his dependents are entitled to a death benefit consisting of an indemnity payment and an allowance for burial expenses. Lab. C. D § 4700-4708. The benefit in cases of total dependency is $ 17,500 for industrial injury resulting in death. Where there is a surviving widow and one or more dependent minor children, the award will be $ 20,500. A burial allowance of up to $ 600/ is allowed in all cases. The death benefit in partial dependency is four times the amount contributed to the support of the dependents by the employee during the year preceding the date of injury, payable at the same weekly rate as the deceased would have received on the basis of temporary total disability indemnity. The total payments are limited to an aggregate of $ 15,000. Lab. C. § 4702.

b) Permanent Disability:

Where the effects of an injury cause a loss of earning power, or impairment of the normal use of a member, or a competitive handicap in the open labor market, there is at least a "partial permanent disability" and the worker will be entitled to compensation based upon the degree of this disability.

The degree of disability is "rated" in terms of "percent of permanent disability". Each one percent of permanent disability equals four weeks of payments. Payments are based on the earnings or earning capacity of the disabled worker, with a maximum of $ 52.50 per week.

To compute a rating, the Division, insurance companies, and attorneys make use of the Permanent Disability Rating Schedule a yardstick which provides a fair method of uniformly evaluating a disability in terms of dollars and cents, taking into consideration the nature of the injury and the age and occupation of the worker, and ability to compete in the open labor market.

c) Temporary Disability:

See enclosed schedule for weekly disability payments.

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APPENDIX

40 U.S.C. § 290

STATE WORKMEN'S COMPENSATION LAWS; EXTENSION TO BUILDINGS AND WORKS OF U.S.

"Whatsoever constituted authority of each of the several States is charged with the enforcement of and requiring compliances with the State workmen's compensation laws of said States and with the enforcement of and requiring compliance with the orders, decisions, and awards of said constituted authority of said States shall have the power and authority to apply such laws to all lands and premises owned or held by the United States of America by deed or act of cession, by purchase or otherwise, which is within the exterior boundaries of any state and to all projects, buildings, constructions, improvements, and property belonging to the United States of America, which is within the exterior boundaries of any State in the same way and to the same extent as if said premises were under the exclusive jurisdiction of the state within whose exterior boundaries such place may be."

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WEEKLY DISABILITY PAYMENTS

For Injuries Sustained On and After September 15, 1961

Weekly Wages	WEEKLY COMPENSATION		Monthly Wages	WEEKLY COMPENSATION	
	Temporary Disability	Permanent Disability		Temporary Disability	Permanent Disability
$32.39	$25.00	$20.00	$140.35	$25.00	$20.00
35.00	25.00	21.61	150.00	25.00	22.30
40.00	25.00	24.70	175.41	25.00	25.00
40.46	25.00	25.00	180.00	25.65	25.65
45.00	27.79	27.79	200.00	28.50	28.50
50.00	30.88	30.88	220.00	31.35	31.35
55.00	33.96	33.96	240.00	34.20	34.20
60.00	37.05	37.05	260.00	37.05	37.05
65.00	40.14	40.14	280.00	39.90	39.90
70.00	43.22	43.22	300.00	42.75	42.75
75.00	46.31	46.31	320.00	45.60	45.60
80.00	49.40	49.40	340.00	48.45	48.45
85.00	52.49	52.49	360.00	51.30	51.30
85.02	52.50	52.50	368.42	52.50	52.50
90.00	55.58	MAX.	380.00	54.15	MAX.
95.00	58.66		400.00	57.00	
100.00	61.75		420.00	59.85	
105.00	64.84		440.00	62.70	
110.00	67.93		460.00	65.55	
113.36 & OVER	70.00		480.00	68.40	
			491.22 & OVER	70.00	

NOTE: The rate of weekly compensation in most cases is based upon the employee's earnings at time of injury, but it may vary depending upon the facts in each case. If the date of your injury was before September 15, 1961, your compensation rate for either temporary or permanent disability may be different from the chart shown above. This is the most recent revision and is dated accordingly. In addition to money payments, tips, meals, room, and other advantages furnished by the employer are to be included in calculating earnings for compensation purposes.